

Hansoh Pharma (3692 HK)

Leading innovative biopharma company

- Innovative drugs continue to drive growth.** Hansoh has successfully transitioned from a traditional generic drug manufacturer to an innovative pharmaceutical company. The Company reported significant growth of sales for innovative drugs in recent years, reaching RMB6.87bn in FY23 (+37.1% YoY), accounting for 68% of Hansoh's total revenue, a substantial increase from 18% in FY20. This shift reflects Hansoh's strong commitment to developing and commercializing innovative drug products. Looking ahead, we anticipate Hansoh's major innovative assets, such as Ameile (aumolertinib), Hengmu (tenofovir amibufenamide), Saint Luolai (pegmolesatide), and Hansoh Xinfu (flumatinib), will continue to drive sales growth. In 2024, we expect aumolertinib's sales to remain robust, driven by volume growth following its inclusion in the NRDL for 1L NSCLC indication since Mar 2023, as well as stable pricing in 2024. Furthermore, we believe the Company's generic medicines have navigated through the most challenging period, as its major generic medicines have been included into the VBP programs. We view generic drugs as a cash cow business for the Company.
- Diversified innovative drug pipeline with global potential.** Hansoh has consistently invested in R&D, with R&D expenses rose 24% YoY to RMB2.10bn in FY23, representing 21% of revenue. Beyond the ongoing development of Ameile for indication expansion, we recognize significant potential in Hansoh's innovative pipeline assets such as ADCs, GLP-1, TYK2 inhibitor, as well as others. In particular, Hansoh's ADC assets have garnered global recognitions from GSK, through two blockbuster out-licensing deals in late 2023, regarding HS-20093 (B7-H3 ADC) and HS-20089 (B7-H4 ADC). We see blockbuster potential in HS-20093 for the treatment of ES-SCLC and other solid tumors. GSK has registered global trials of these two ADCs in 2H24. Hansoh is also developing an EGFR/cMet ADC, which is projected to enter clinical studies by end-2024. In the GLP-1 franchise, Hansoh launched Fulaimai in China in May 2019 and is currently developing a weekly GLP-1/GIP dual agonist HS-20094, as well as an oral GLP-1 drug HS-10501. Hansoh is among the frontrunners in the GLP-1 field in China. We expect HS-20094 to enter Ph3 study for obesity in 2H24.
- Solidifying the leading position through extensive global collaborations.** Hansoh is solidifying its leading position through extensive global collaborations. Besides its robust internal R&D efforts, Hansoh actively seeks collaboration opportunities worldwide to strengthen its product pipeline. Hansoh has forged several in-licensing partnerships with both overseas and domestic entities, including Qyuns Therapeutics, Biotheus, KiOmed Pharma, and Atomwise, among others. Leveraging its R&D and commercialization capabilities, we envision Hansoh evolving into an integrated platform for biotech companies seeking partnerships in the Chinese market.
- Initiate at BUY with TP of HK\$22.06.** In FY24E, we expect the Company's total revenue to increase 19% YoY, reaching RMB12.0bn. We anticipate Hansoh's total innovative drug sales to grow 37% YoY to RMB9.5bn in FY24E, accounting for 79% of the Company's total revenue. Excluding the impact of collaboration payment from GSK in FY23 and FY24, we expect the Company's organic revenue growth to reach 12%/ 14% YoY in FY24E/ 25E, respectively. We expect the Company's attributable net profit to increase 24% and decrease 22% YoY in FY24E and FY25E to RMB4.1bn/ 3.2bn, respectively. We derived our DCF-based price target of HK\$22.06 (WACC: 8.67%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY22A	FY23A	FY24E	FY25E	FY26E
Revenue (RMB mn)	9,382	10,104	12,034	12,191	13,878
YoY growth (%)	(5.6)	7.7	19.1	1.3	13.8
Net profit (RMB mn)	2,584	3,278	4,075	3,190	3,594
YoY growth (%)	(4.8)	26.9	24.3	(21.7)	12.7
EPS (Reported) (RMB)	0.44	0.55	0.69	0.54	0.61
P/E (x)	36.1	28.5	23.0	29.4	26.1
R&D expenses (RMB mn)	(1,693)	(2,097)	(2,350)	(2,621)	(2,914)
Admin expenses (RMB mn)	(597)	(710)	(796)	(896)	(1,006)

Source: Company data, Bloomberg, CMBIGM estimates

BUY

Target Price **HK\$22.06**
 Up/Downside **28.0%**
 Current Price **HK\$17.24**

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Stock Data

Mkt Cap (HK\$ mn)	102,330.6
Avg 3 mths t/o (HK\$ mn)	68.1
52w High/Low (HK\$)	19.00/9.61
Total Issued Shares (mn)	5935.7

Source: FactSet

Shareholding Structure

Sunrise Trust Trustee	65.7%
JQC International Limited	16.0%

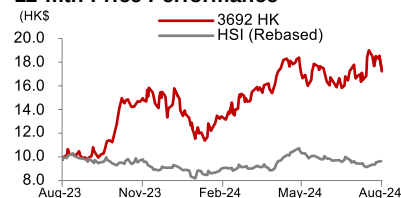
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	1.3%	0.5%
3-mth	-0.2%	6.9%
6-mth	29.6%	23.1%

Source: FactSet

12-mth Price Performance



Source: FactSet

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Investment thesis

Innovative drugs continue to drive growth

We expect Hansoh to maintain strong momentum in growing its revenue driven by sales of innovative drug products. The Company has successfully transitioned from a traditional generic drug manufacturer to an innovative pharmaceutical company. Sales of Hansoh's innovative drug products have experienced significant growth in recent years, reaching RMB6.87bn in FY23 (+37.1% YoY). In FY23, Hansoh achieved total revenue of RMB10.10bn, representing 7.7% year-over-year growth. Notably, revenue from innovative drugs in FY23 accounted for 68% of Hansoh's total revenue, a substantial increase from 18% in FY20. This shift reflects the Company's strong commitment to developing and commercializing innovative drugs. Looking ahead, we anticipate Hansoh's major innovative assets, such as Ameile (aumolertinib), Hengmu (tenofovir amibufenamide), Saint Luolai (pegmolesatide), and Hansoh Xinfu (flumatinib), will continue to drive sales growth in the coming years.

As the first domestically developed third-generation EGFR-TKI in China, Ameile (aumolertinib) enjoys first-mover advantages. Aumolertinib has consistently shown strong sales growth, with FY23 sales rising nearly 20% YoY. In 2024, we anticipate aumolertinib's sales to remain robust, driven by volume growth subsequent to its inclusion in the National Reimbursement Drug List (NRDL) for first-line NSCLC indication since Mar 2023, and stable pricing in 2024. Aumolertinib's compelling efficacy and safety profiles, particularly for patients with CNS metastases, bolster its market share in China. Moreover, the expansion of indications will further enhance aumolertinib's sales potential, including aumolertinib as adjuvant therapy for NSCLC, maintenance treatment for unresectable Stage III NSCLC, and in combination with chemotherapy for first-line NSCLC. Hansoh submitted the sNDA of aumolertinib for NSCLC adjuvant treatment in Jul 2024, with approval anticipated in mid-2025 and potential NRDL inclusion by early 2026. In Aug 2024, the Company also submitted the sNDA of aumolertinib for the unresectable Stage III maintenance treatment. We have confidence in the management's sales target of RMB6.0bn for aumolertinib in FY26E and expect the drug's peak sales to reach around RMB8.2bn by 2030E.

For the treatment of patients with chronic hepatitis B, TDF, TAF and ETV have already been included in the national VBP (Volume-Based Procurement), while Hengmu (tenofovir amibufenamide/TMF) is currently free from VBP risk as the drug is positioned as an innovative product in China. Hengmu has experienced strong sales momentum. We expect Hengmu to further gain market share in the sizeable hepatitis B market, thanks to its superior safety profile and non-inferior efficacy compared to TDF, in our view.

Saint Luolai (pegmolesatide) is the only EPO mimetic peptide approved worldwide and the only monthly EPO in China for the treatment of renal anemia. Administered subcutaneously on a monthly basis, pegmolesatide greatly reduces the annual administration frequency, significantly improving patient compliance. Pegmolesatide has shown superior efficacy in raising hemoglobin levels and comes with an improved safety profile compared to conventional short-acting rhEPO products. This positions pegmolesatide to capture a meaningful share of the Chinese renal anemia market. Importantly, the inclusion of pegmolesatide in the NDRL since early 2024 is expected to improve its affordability and accessibility for patients, further enhancing its market position.

Generic drugs to be cash cow business

We believe that the Company's generic medicines have navigated through the most challenging period. Previously, Hansoh's major generic drugs were olanzapine (奥氮平), pemetrexed (培美曲塞), gemcitabine (吉西他滨), repaglinide (瑞格列奈), tigecycline (替加环素), imatinib (伊马替尼), decitabine (地西他滨), and rabeprazole (雷贝拉唑). As all of these major generic drugs have already been included in the Volume-Based Procurement (VBP) programs, the proportion of revenue from generic drugs have decreased from 82.0% in 2020 to 32.1% in 2023. While the Company's generic business may decline mildly because more generic drugs will be covered by VBP, we expect Hansoh's generic drug operations to continue contributing to the Company's overall profitability in coming years.

Diversified innovative product pipeline with global potential

Hansoh has consistently demonstrated a strong commitment to the development of innovative products. The Company's annual R&D costs have grown at a 18.9% CAGR from RMB881mn in FY18 to RMB2,097mn in FY23. The R&D expenses to revenue ratio has also witnessed a substantial rise, from 11.4% in FY18 to 20.8% in FY23.

As of the end of 2023, Hansoh was conducting more than 50 clinical trials, encompassing over 30 innovative drug products. The Company aims to bring 8-10 new molecules to the clinical stage of development annually, further strengthening its innovative product pipeline. Hansoh continues to broaden the indication coverage of Ameile for various indications. We also recognize the great potential of the Company's R&D advancement in areas such as Antibody Drug Conjugates (ADC) assets, GLP-1 assets, TYK2 inhibitor, among others.

Hansoh's ADC assets have garnered recognition from global MNC. In late 2023, Hansoh brokered agreements to out-license the ex-China rights to two of its ADC assets - HS-20093 (B7-H3 ADC) and HS-20089 (B7-H4 ADC) - to GSK. GSK has registered Ph1 trials of these two assets. Within China, Hansoh is actively developing HS-20093 (B7-H3 ADC) for solid tumors, including a Ph3 in 2L ES-SCLC, a Ph3 in LS-SCLC, and multiple Ph2 studies in head and neck cancers, mCRPC, sarcoma, and others. We identify blockbuster potential for HS-20093 in SCLC and other solid tumors. HS-20089 (B7-H4 ADC) is also undergoing Ph2 studies for the treatment of ovarian cancer and endometrial cancer in China, with first-in-class/best-in-class potential. Additionally, Hansoh has in-licensed the China rights for an EGFR/cMET bispecific antibody (HS-20117) and is developing an EGFR/cMET ADC (HS-20122) accordingly, with global rights.

In the GLP-1 franchise, Hansoh's Fulaimai (PEGylated loxenatide, GLP-1), launched in May 2019, was the first domestic innovative weekly GLP-1 hypoglycemic drug for the treatment of Type 2 diabetes. The Company is also developing a new-generation, weekly-administered GLP-1/GIP dual agonist (HS-20094). Hansoh is evaluating HS-20094 in Ph2 trials for diabetes and obesity in China, and plans to initiate a Ph3 study for obesity in 2H24. Furthermore, Hansoh's HS-10501, an innovative oral GLP-1 drug, is currently in Ph1a stage.

Solidifying the leading position through broad collaborations

In addition to its internal R&D efforts, Hansoh actively pursues global collaboration opportunities to enhance its product pipeline. This is achieved through in-licensing partnerships, platform collaborations, and out-licensing agreements. Hansoh has established various in-licensing partnerships with both international and domestic companies, including Qyuns Therapeutics, Biotheus, KiOmed Pharma, Atomwise, among others. Leveraging its R&D and commercialization capabilities, we anticipate that Hansoh will evolve into an integrated platform for biotech companies seeking partnerships in China. Furthermore, Hansoh successfully out-licensed two of its internally developed ADC assets, HS-20089 (B7-H4 ADC) and HS-20093 (B7-H3 ADC), to GSK in late 2023. These deals not only validate Hansoh's R&D capabilities, but also accelerate the global development of these drug candidates.

Initiate at BUY with TP of HK\$22.06

In FY24E, we expect the Company's total revenue to increase 19% YoY, reaching RMB12.0bn. We anticipate Hansoh's total innovative drug sales to grow 37% YoY to RMB9.5bn in FY24E, accounting for 79% of the Company's total revenue. Excluding the impact of collaboration payment from GSK in FY23 and FY24, we expect the Company's organic revenue growth to reach 12%/ 14% YoY in FY24E/ 25E, respectively. We expect the Company's attributable net profit to increase 24% YoY and decrease 22% YoY in FY24E and FY25E to RMB4.1bn/ 3.2bn, respectively, with the fluctuations mainly due to the impact from BD income. We derived our DCF-based price target of HK\$22.06 (WACC: 8.67%, terminal growth rate: 3.0%).

Investment risks

1) Failure of clinical development or regulatory approvals of drug candidates. 2) Competition of approved products both in China and overseas markets. 3) Uncertainties in the collaboration with GSK and other strategic partners.

A leading biopharmaceutical company

Established in 1995, Hansoh Pharma has evolved from a traditional generic drug company into a leading innovative biopharmaceutical company in China. Hansoh mainly focuses on the fields of oncology, CNS diseases, metabolic diseases, and anti-infections. The Company was listed in the Stock Exchange of Hong Kong (3692.HK) in Jun 2019.

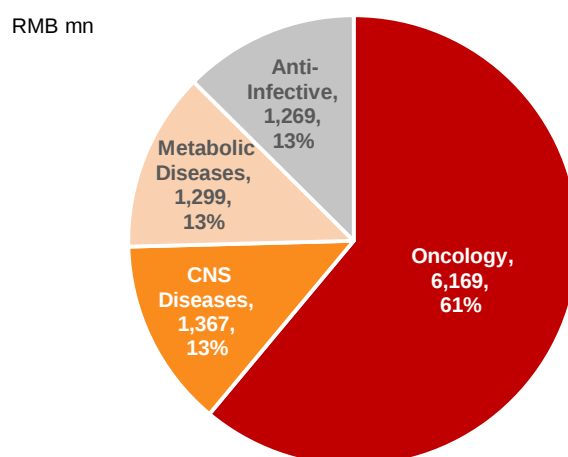
Hansoh Pharma has already commercialized 8 innovative drugs, covering therapeutic areas such as oncology, CNS diseases, metabolic diseases, and infection.

As of the end of 2023, the Company was conducting more than 50 clinical trials, encompassing over 30 innovative drug products. Hansoh aims to bring 8-10 new molecules to the clinical stage of development annually, further strengthening its innovative product pipeline. Hansoh continues to broaden the indication coverage of Ameile (aumolertinib) for various indications. We also recognize the great potential of the Company's R&D advancement in areas such as Antibody Drug Conjugates (ADC) assets, GLP-1 assets, TYK2 inhibitor, among others.

Innovative drugs contributing the majority of revenue

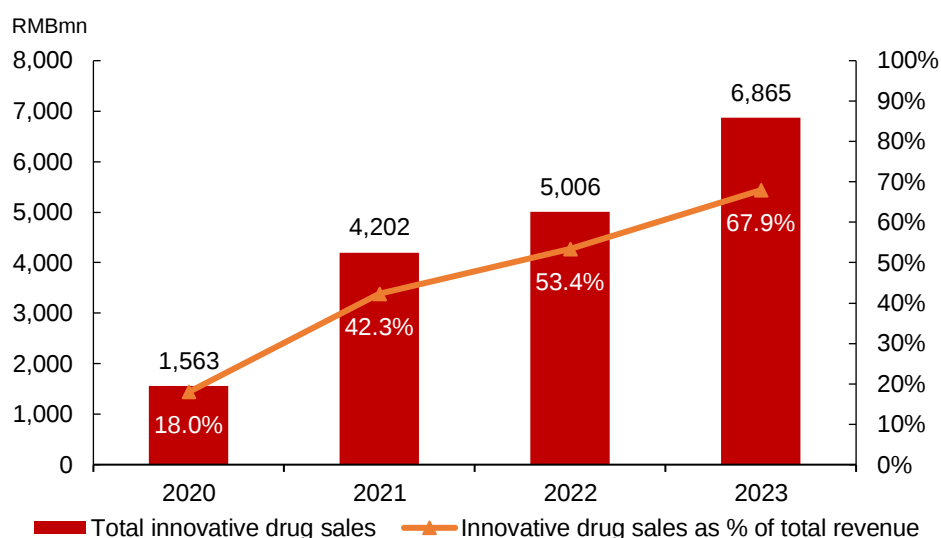
Hansoh achieved a revenue of RMB10.10bn in FY23 (+7.7% YoY). Among the Company's focused therapeutic areas, oncology played a significant role, accounting for 61% (RMB6.17bn) of the total revenue in FY23. In addition, CNS disease drugs, metabolic disease drugs and anti-infection drugs each represented approximately 13% of the total revenue in FY23.

Figure 1: Hansoh's FY23 revenue breakdown



Source: Company data, CMBIGM

Hansoh has undergone a successful transition from a traditional generic drug company to an innovative drug company. Sales from innovative drugs have experienced significant growth in recent years, reaching RMB6.87bn in FY23, up 37.1% YoY. In FY23, the percentage of revenue from innovative drugs accounted for 68% of the total revenue, a substantial increase from 18% in FY20. This shift highlights the Company's commitment to developing and commercializing innovative pharmaceutical products. Looking ahead, we expect the Company will continue to grow its innovative drug portfolio with rich innovative drug pipelines.

Figure 2: Hansoh's innovative drug revenue

Source: Company data, CMBIGM

As of Aug 2024, the Company had a commercial portfolio of eight innovative drugs (see table below) across its focused therapeutic areas, including two in-licensed assets. All of these innovative drugs have been included in the NRDL as of Aug 2024. Among these marketed innovative drugs, we expect Ameile (aumolertinib), Hengmu (tenofovir amibufenamide), Saint Luolai (pegmolesatide), Hansoh Xinfu (flumatinib), and Fulaimei (PEG-loxenatide) to be the primary revenue drivers.

Figure 3: Commercial innovative drugs of Hansoh

Sector	Drug name (Chinese)	Drug name (English)	MoA	Date of approval	Approved indications	Partner	Current NRDL period
Oncology	阿美乐 (甲磺酸阿美替尼片)	aumolertinib mesilate tablets	EGFR-TKI	2020.3	2L NSCLC with EGFR exon20 T790M mutation who have progressed on or after EGFR-TKI	-	2023.3.1-2024.12.31
				2021.12	1L NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitute mutation	-	
	豪森斯福 (甲磺酸氟马替尼片)	flumatinib mesylate tablets	Bcr-Abl inhibitor	2019.11	1L Ph+ CML in chronic phase	-	2023.3.1-2024.12.31
	希维奥 (塞利尼索)	selinexor	XPO1 inhibitor	2021.12	R/R multiple myeloma	In-licensed from Antengene	2024.1.1-2025.12.31
Metabolic diseases and others	孚来美 (聚乙二醇洛塞那肽注射液)	PEG-loxenatide for injection	GLP-1R agonist	2019.5	Type II diabetes	-	2023.3.1-2024.12.31
	圣罗莱 (培莫沙肽注射液)	pegmolesatide injection	EPO receptor agonist	2023.6	Anemia in CKD adult patients not on dialysis and on dialysis	-	2024.1.1-2025.12.31
CNS diseases	昕越 (伊奈利珠单抗注射液)	inebilizumab injections	CD19 mAb	2022.3	AQP4-antibody-positive NMOSD	In-licensed from Viela Bio	2023.3.1-2024.12.31
Anti-infective diseases	迈灵达 (吗啉硝唑氯化钠注射液)	merinidazole sodium chloride for injection	nitroimidazoles	2014.2	Infections caused by bacteria (gynecological pelvic inflammatory, appendicitis)	-	Regular list
	恒沐 (富马酸艾米替诺福韦片)	tenofovir amibufenamide tablets	HIV-1 RT inhibitor	2021.6	Chronic hepatitis B virus (HBV) infection	-	2024.1.1-2025.12.31

Source: Company data, CMBIGM. Note: As of Aug 2024.

Ameile (aumolertinib), to continue its strong growth momentum driven by indication expansion

Aumolertinib, the first domestic innovative third-generation EGFR-TKI drug, has been approved in China in Mar 2020 for 2L NSCLC patients with T790M mutation who have progressed on or after EGFR-TKI therapy. 1st/2nd generation EGFR-TKIs can significantly improve patient prognosis for patients with EGFR-mutant NSCLC, but those patients often develop acquired resistance after 9–14 months of treatment. These resistance mechanisms are complex and diverse, with the EGFR exon 20 T790M mutation being the most common, accounting for approximately 50% ([link](#)). Aumolertinib's approval for these patients enables the drug to enjoy a first mover advantage in China, in our view.

Aumolertinib was further approved for 1L NSCLC with EGFR exon 19 deletions or exon 21 L858R substitute mutation in Dec 2021. Aumolertinib has been covered by the NRDL since Mar 2021 for the 2L NSCLC indication. In Mar 2023, the NRDL started to cover aumolertinib for the 1L NSCLC indication with a significant price cut of 42.7%. The revenue from aumolertinib increased by nearly 20% in FY23 driven by the significant volume growth which has offset the impact from price cut. With stable pricing in 2024, we expect aumolertinib to maintain strong volume growth with sales increasing around 23% YoY in FY24E. Additionally, we expect aumolertinib's pricing to remain largely stable during the NRDL renewal in end-2024.

Aumolertinib to further expand indication coverage

Indication expansion will further enhance the sales potential of aumolertinib, in our view. Hansoh is conducting multiple Ph3 trials of aumolertinib to expand its indications in early settings, including adjuvant Stage II-IIIB EGFR-m NSCLC (mono), maintenance therapy for unresectable EGFR-m Stage III NSCLC (mono), and 1L EGFR-m NSCLC (combo chemo). The Company is also exploring the potential of aumolertinib in combo with other innovative drug candidates, including combo with HS-10241 (cMET inhibitor) for EGFR-TKI resistant MET+ NSCLC and combo with HS-20117 (EGFR-MET bsAb) for 1L locally advanced or metastatic EGFR-m nsq-NSCLC. We are confident towards the management's RMB6.0bn sales target of aumolertinib in 2026E.

AstraZeneca's 3rd generation (3G) EGFR-TKI osimertinib was approved for adjuvant NSCLC (Stage IB-IIIA) in China in 2021 and late 2020 in the US, becoming the first and only EGFR-TKI for adjuvant treatment. Similarly, Hansoh has conducted a Ph3 trial (NCT04687241) of aumolertinib in the similar setting (Stage II-IIIB) with the sNDA submitted in China in Jul 2024. Upon the approval, we expect aumolertinib to be the second EGFR-TKI approved for adjuvant EGFR-m NSCLC treatment in China. The adjuvant Stage II-IIIB NSCLC indication has large revenue potential due to the long treatment duration and the increasing EGFR TKI adoption rate. We expect aumolertinib to receive the approval for adjuvant EGFRm NSCLC in mid-2025 and to obtain NRDL coverage of the indication since early 2026.

Osimertinib is under FDA sNDA review for unresectable Stage III EGFRm NSCLC after chemoradiotherapy (CRT), based on promising results in the LAURA trial. Hansoh has initiated a Ph3 trial of aumolertinib in the similar setting in China (NCT04951635) in Mar 2021. The sNDA based on this trial was submitted in Aug 2024. Globally, 20-30% of the 2 million diagnosed NSCLC patients have Stage III disease, among which 60-90% are unresectable ([link](#)). The current SoC for these patients is CRT followed by durvalumab (PD-L1).

To further enhance its SoC positioning in 1L EGFRm NSCLC, osimertinib plus chemo was approved by the FDA and the NMPA for 1L NSCLC in 1H24 based on the FLAURA2 trial. The combo therapy significantly improved mPFS compared to osimertinib monotherapy (mPFS 25.5 vs 16.7 months, HR 0.62, p<0.0001). Hansoh has been conducting a Ph3 trial of aumolertinib in combination with chemo for 1L EGFRm NSCLC since Aug 2021, and we expect the sNDA submission to happen by end-2024. The treatment landscape for EGFR-mutated NSCLC patients may be on the brink of a new era with the prospective combination of EGFR-TKI and chemotherapy. This treatment approach could be particularly beneficial for patients who are tolerant and amenable to undergoing chemotherapy.

Figure 4: Pivotal studies of aumolertinib

Indications	Regimen	Trial ID	Phase	Region	Start date	Est primary complete date	Primary endpoint
Adjuvant Stage II-IIIB EGFR-m NSCLC with exon 19 deletion or exon 21 L858R mutation	mono vs placebo	NCT04687241 (sNDA submitted in Jul 2024)	Ph3	China	2021-04	2026-01	DFS
Maintenance therapy for unresectable Stage III EGFRm NSCLC after chemoradiation	mono vs placebo	NCT04951635 (sNDA submitted in Aug 2024)	Ph3	China	2021-03	2024-07	PFS
1L EGFR-m NSCLC with exon 19 deletion or exon 21 L858R mutation	mono vs Gefitinib	NCT03849768/ AENEAS (approved)	Ph3	China	2019-02	2021-01	PFS
1L EGFR-m NSCLC	aumolertinib +chemo vs aumolertinib	NCT04923906	Ph3	China	2021-08	2024-01	PFS
1L EGFRm nsq-NSCLC (Stage IIIB/IIIC/IV)	Ph1b: aumolertinib +HS-20117 (EGFR-MET bsAb) Ph3: aumolertinib +HS-20117 vs aumolertinib	NCT06417008	Ph1b/3	-	2024-06 (est)	2026-06	Ph1b ORR; Ph3 PFS
1L EGFR-m NSCLC (pts with uncommon EGFR mutation, i.e. exon 21 L861Q, exon 18 G719X or exon 20 S768I)	mono vs chemo	NCT04951648	Ph3	China	2021-07	2023-10 (est)	PFS
Post-EGFR-TKI NSCLC with MET amplification	+ HS-10241 (cMET) vs chemo	NCT06110663	Ph3	-	2023-12 (est)	2024-12	PFS
EGFR-TKI post NSCLC with exon 20 T790M	mono, single arm	NCT02981108/ APOLLO (approved)	Ph2	China	2017-05	2019-01	ORR

Source: PharmCube, CMBIGM. Note: as of Aug 2024

Competitive profile of aumolertinib for EGFRm NSCLC patients

Aumolertinib shows compelling efficacy and safety profile, supporting its leading market position in China, in our view. Compared with other 3rd generation EGFR-TKI drugs, i.e. osimertinib and furmonertinib, aumolertinib demonstrated better efficacy for the treatment of 1L NSCLC patients with EGFR exon 19 deletion or L858R mutations, with lower PFS HR of 0.46, compared to osimertinib's 0.56 and furmonertinib's 0.58 for Chinese patients. For patients with CNS metastases, aumolertinib also presented strong efficacy, with a PFS HR of 0.32, vs furmonertinib's HR of 0.40. Additionally, in cross-trial comparison, aumolertinib has more favorable safety profiles compared with peers, in terms of the rate of rash, diarrhea and ILD. The discontinuation rate observed in aumolertinib's trials are also lower than that of its peers. With superior profile and wide indication expansion potential, we expect aumolertinib to further take share in China's market, even at a higher retail price than osimertinib (RMB72.6k annual cost of aumolertinib vs RMB59.6k of osimertinib).

Figure 5: Comparison of 3G EGFR-TKIs in 1L NSCLC with EGFR exon 19 deletion or L858R mutations

Drug	aumolertinib	osimertinib	osimertinib	furmonertinib	befotertinib
Brand name	Ameile (阿美乐)	Tagrisso (泰瑞沙)	Tagrisso (泰瑞沙)	Aifusha (艾氟沙)	Saimeina (赛美纳)
Company	Hansoh	AstraZeneca	AstraZeneca	Allist Pharma	Betta Pharma
Trial ID	AENEAS	FLAURA	FLAURA-China	FURLONG	NCT04206072
Regimen	aumolertinib vs gefitinib	osimertinib vs gefitinib or erlotinib	osimertinib vs gefitinib or erlotinib	furmonertinib vs gefitinib	befotertinib vs icotinib
Stage	Ph3 (China)	Ph3 (global)	Ph3 (China)	Ph3 (China)	Ph3 (China)
Primary endpoint	PFS	PFS	PFS	PFS	PFS
Patient number	214 vs 215	279 vs 277	71 vs 65	178 vs 179	182 vs 180
mPFS	19.3m vs 9.9m HR=0.46	18.9m vs 10.2m HR=0.46	17.8m vs 9.8m HR=0.56	20.8m vs 11.1m HR=0.58	22.1m vs 13.8m HR=0.49
mPFS in pts with CNS metastases	15.3m and 8.2m, HR=0.38 (n=56 vs 59, data cutoff in Jan 2021, PFS based on all tumor progression) 29.0m vs 8.3m, HR=0.323 (n=51 vs 55, data cutoff in Aug 2021, PFS based on intracranial tumor progression)	15.2m vs 9.6m HR=0.47 (based on all tumor progression)	HR=0.66 (0.30-1.38) CNS progression 3% vs 20%	20.8m vs 9.8m, HR=0.40 (based on intracranial tumor progression)	--
mDoR	18.1m vs 8.3m	17.2m vs 8.5m	--	19.7m vs 11.0m	--
mOS			33.1m vs 25.7m HR=0.85 (0.56-1.29)		
AE (Gr>=3)	36.4% vs 35.8%	34% vs 45%	54% vs 28%	11% vs 18% (TRAE Gr>=3)	30% vs 8% (TRAE Gr>=3)
Rash	23.4% vs 41.4%	58% vs 78%	37% vs 39%	18% vs 41%	
Diarrhea	16.4% vs 35.8%	58% vs 57%	24% vs 29%	30% vs 42%	
ILD	0.9% vs 0.5%	4% vs 2%	3% vs 3%	0.6% vs 0.6%	
Dose interruptions	16.8% vs 24.7%	25% vs 24%	21% vs 11%	3% vs 3%	
Discontinuation	3.7% vs 5.1%	13% vs 18%	13% vs 6%	3% vs 2%	
TRAE leading to death	1 pt in each of the cohorts, both was unable to confirm if drug-related				1% vs 1% (2 pts vs 1 pts)
Source	Link1 , Link2	Link	Link	Link1 , Link2	Link

Source: PubMed, CMBIGM

Osimertinib strengthened its position as a global SoC position through label expansion

Tagrisso (osimertinib), developed by AstraZeneca, is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including against CNS metastases. Osimertinib has been approved for EGFR-TKI resistant NSCLC with T790M, 1L EGFRm NSCLC and adjuvant Stage IB-IIIa NSCLC.

Figure 6: Osimertinib's approved indications and indications under NDA review

Indication	Date of initial approval	Clinical trial registration no.	Regimen	Regions approved
EGFR-TKI post NSCLC with exon 20 T790M	2015-11-13	NCT02151981	Osimertinib vs chemo	US, China, EU, etc
1L EGFRm NSCLC	2018-4-18	NCT02296125	Osimertinib vs Gefitinib or Erlotinib	US, China, EU, etc
Adjuvant treatment of Stage IB-IIIa EGFRm NSCLC following resection with/without prior adjuvant chemo	2020-12-18	NCT02511106	Osimertinib vs placebo	US, China, EU, etc
1L EGFRm NSCLC	2024-02-16	NCT04035486	Osimertinib + chemo vs Osimertinib	US, China
Maintenance therapy for unresectable Stage III EGFRm NSCLC who has not progressed chemoradiation	--	NCT03521154	Osimertinib vs placebo	NDA in US (PDUFA 4Q24), NDA in China (2024-06)

Source: Company data, CMBIGM

Osimertinib in combination with chemo was approved by the FDA in Feb 2024 and by the NMPA in Jun 2024 for 1L NSCLC with exon 19 deletions or exon 21 L858R mutations, based on the results of FLAURA2 study. Osimertinib plus chemo significantly improved PFS vs osimertinib monotherapy with mPFS of 25.5 months vs 16.7 months and HR of

0.62 ($p < 0.0001$). Osimertinib plus chemo also demonstrated favourable trend in the secondary endpoint of OS vs osimertinib mono, with HR of 0.75 (95% CI, 0.57-0.97, 41% data maturity, [link](#)). Grade 3 or higher AEs of any causes occurred in 64% of patients in the osimertinib plus chemotherapy arm versus 27% in the osimertinib monotherapy arm. We think the combination therapy further strengthened osimertinib's position as global SoC for 1L EGFRm NSCLC.

Osimertinib is the only targeted therapy approved for the adjuvant treatment of Stage IB-IIIA EGFRm NSCLC, following the results from the ADAURA Ph3 trial. AstraZeneca is poised to extend the application of osimertinib even earlier into the treatment sequence through ongoing Ph3 trials, including ADAURA2 for adjuvant treatment in earlier Stage IA2-IA3, and NeoADAURA in the neoadjuvant setting. Results from the NeoADAURA trial are anticipated by late 2024.

For unresectable Stage III EGFRm NSCLC following chemoradiotherapy (CRT), the sNDA is currently under review by the FDA with priority review and Breakthrough Therapy Designation (BTD). This regulatory advancement is grounded on findings from the LAURA trial. The PDUFA date is scheduled for 4Q24. In the LAURA trial ([link](#)), osimertinib extended the mPFS by more than three years compared to the placebo (39.1 months vs 5.6 months) for unresectable Stage III EGFRm NSCLC following CRT, and reduced the risk of disease progression or death by 84% compared to the placebo (HR 0.16, $p < 0.001$).

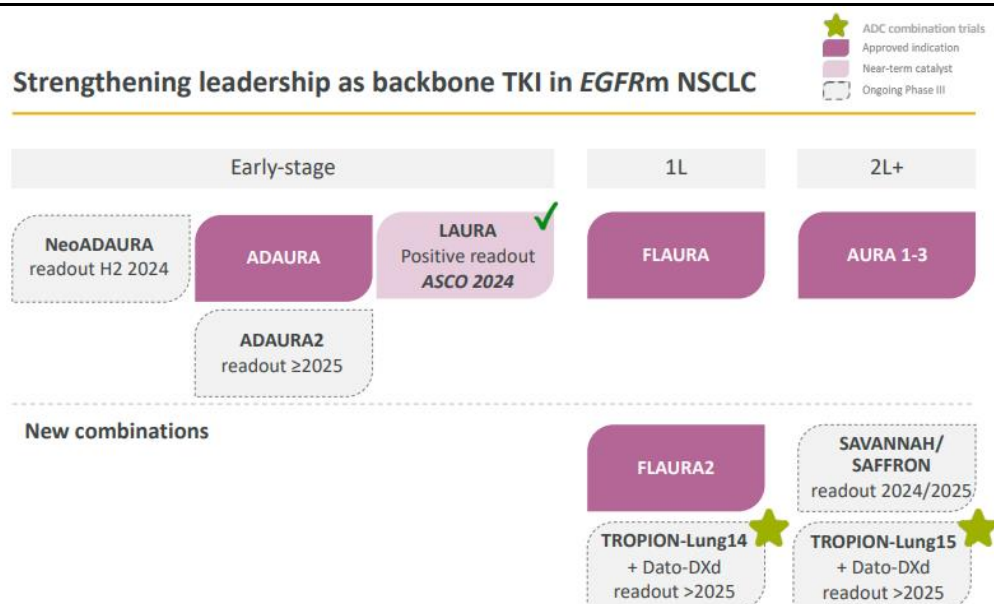
Additionally, several Ph3 trials are currently underway to evaluate osimertinib in combination therapies. These studies are exploring its use alongside chemotherapy for 2L NSCLC patients who did not respond to first-line osimertinib treatment. Other combinations being tested include osimertinib with Dato-DXd (a TROP2 ADC) for both first-line EGFRm NSCLC and osimertinib-resistant EGFRm NSCLC, as well as osimertinib paired with savolitinib for MET-positive, osimertinib-resistant NSCLC patients.

Figure 7: Ph3 trials of osimertinib

Trial ID	Indication	Status	Regimen	Date of posting	(Estimated) date of completion
NCT04351555/ NeoADAURA	Neoadjuvant EGFRm NSCLC	Readout in 2H24E	Osimertinib with or without chemo vs chemo	2020-04-17	2029-06-13
NCT05120349/ ADAURA2	Adjuvant therapy for resected Stage IA2-IA3 EGFRm NSCLC	Readout >2025E	Osimertinib vs placebo	2021-11-15	2032-11-01
NCT02511106/ ADAURA	Adjuvant therapy for resected Stage IB-IIIA EGFRm NSCLC following resection with/without adjuvant chemo	NDA approved	Osimertinib vs placebo	2015-07-29	2029-01-31
NCT03521154/ LAURA	Maintenance therapy for unresectable Stage III EGFRm NSCLC who has not progressed chemoradiation	PDUFA in 4Q24 in the US; NDA in Jun 2024 in China	Osimertinib vs placebo	2018-05-11	2026-06-29
NCT03833154/ PACIFIC-4	Stage I/II EGFRm NSCLC	-	Single arm following SBRT	2019-02-06	2028-04-04
NCT04035486/ FLAURA2	1L EGFRm NSCLC	NDA approved (US, China); To be approved in EU in 2H24E	Osimertinib + chemo vs Osimertinib mono	2019-07-29	2026-06-03
NCT02296125/ FLAURA	1L EGFRm NSCLC	NDA approved	Osimertinib vs Gefitinib or Erlotinib	2014-11-20	2025-01-31
NCT06350097/ TROPION-Lung14	1L EGFRm NSCLC	Readout >2025E	Dato-DXd + Osimertinib vs Osimertinib	2024-04-05	2032-05-25
NCT06417814/ TROPION-Lung15	Post-Osimertinib EGFRm NSCLC	Readout >2025E	Dato-DXd with or without Osimertinib vs chemo	2024-05-16	2028-02-08
NCT05261399/ SAFFRON	2L Post-Osimertinib MET+ EGFRm NSCLC	Readout in 2H25E (SAVANNAH Ph2 readout in 2H24E; China 1L SANVO and 2L SACHI to readout in 2H24)	Savolitinib+ Osimertinib vs chemo	2022-03-02	2026-12-17
NCT04765059/ COMPEL	2L EGFRm NSCLC who failed 1L Osimertinib	-	Osimertinib + chemo vs chemo	2021-02-21	2024-12-30
NCT02454933/ CAURAL	EGFR TKI post NSCLC with T790M	-	Osimertinib+Durvalumab vs Osimertinib	2015-05-27	2023-06-21
NCT02151981/ AURA3	EGFR TKI post NSCLC with T790M	NDA approved	Osimertinib vs chemo	2014-06-02	2023-12-29

Source: AstraZeneca, CMBIGM. Note: As of Aug 2024

Figure 8: Label expansion strategy of osimertinib

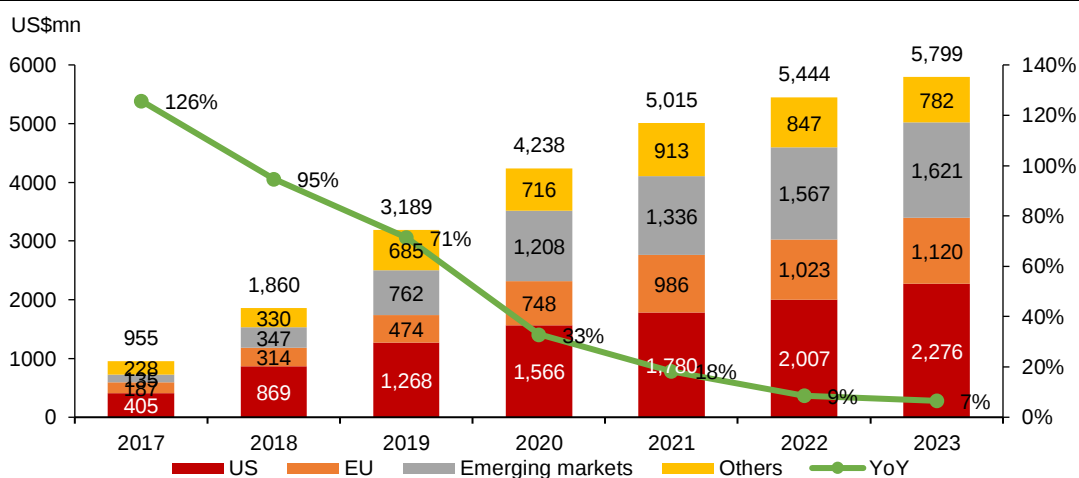


Source: AstraZeneca, CMBIGM. Note: As of Aug 2024

In FY23, osimertinib reached global sales of US\$5.80bn, with the majority (59%) stemming from the US and EU. While the sales growth has moderated, we anticipate osimertinib will maintain its market leader position through indication expansion. In the US, osimertinib is currently the only marketed third-generation EGFR-TKI. J&J's lazertinib was recently approved in Aug 2024, in combo with amivantamab for 1L NSCLC.

Lazertinib, developed by J&J, is in Ph3 studies in combination with amivantamab (an EGFR/MET bispecific antibody) both with and without chemotherapy for post-osimertinib NSCLC and first-line (1L) NSCLC with exon 19 deletions or L858R mutations. However, due to safety concerns regarding the triple combination of lazertinib, amivantamab, and chemotherapy, J&J did not file a BLA for lazertinib for post-osimertinib NSCLC. Instead, a BLA for amivantamab combined with chemotherapy in this setting was filed in late 2023 based on the MARIPOSA trial. For 1L NSCLC with exon 19 deletions or L858R, a BLA for the combination of lazertinib and amivantamab was approved by the FDA in Aug 2024.

Figure 9: Global sales of osimertinib



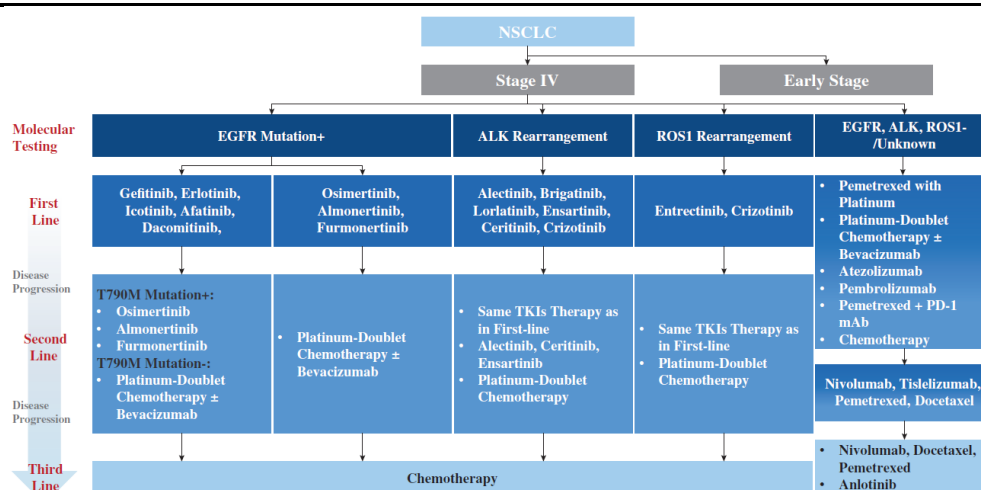
Source: AstraZeneca, CMBIGM

Growing 3G EGFR TKI market in China

Globally, three generations of EGFR-TKIs have been developed, with the first and second generations predominantly targeting EGFR exon 19 deletions and exon 21 L858R substitutions. These mutations account for approximately 45% and 40% (85% in total) of EGFR mutations, respectively. In contrast, EGFR exon 20 insertions represent 4-10% of EGFR mutations. Patients treated with first and second-generation EGFR-TKIs often develop acquired resistance after 9-14 months, with the EGFR exon 20 T790M mutation being the most common mechanism of resistance, accounting for about 50% ([link](#)).

The third-generation (3G) EGFR-TKIs, including osimertinib, aumolertinib, furmonertinib, and befotertinib, are effective for treating patients with the T790M mutation. More critically, 3G EGFR-TKIs have become the global standard of care (SoC) for first-line treatment of EGFRm NSCLC, due to their superior efficacy compared to the first and second generations. The third-generation EGFR-TKIs currently hold a dominant position in the EGFR-TKI market. According to Frost & Sullivan (F&S) data, as of 2022, third-generation EGFR-TKIs accounted for approximately 73% of the total EGFR-TKI market share in China, with projections suggesting an increase to 94% by 2033.

Figure 10: Treatment paradigm of Stage IV NSCLC with AGAs



Source: CSCO, CMBIGM

Figure 11: Approved 3G EGFR-TKIs in China

Drug name	Chinese name	Brand name	Company	Approved indications in China (date of approval)	Current NRDL coverage	Annual cost (RMB per year)
osimertinib	奥希替尼	Tagrisso/泰瑞沙	AstraZeneca	2L (2017-03); 1L (2019-09 mono, 2024-06 combo chemo); Adjuvant (2021-04)	2L; 1L (mono); adjuvant (2024.01-2024.12)	59,594
aumolertinib	阿美替尼	阿美乐	Hansoh	2L (2020-03); 1L (2021-12)	2L; 1L (2023.03-2024.12)	72,576
furmonertinib	伏美替尼	艾弗沙	Allist Pharma, ArriVent	2L (2021-03); 1L (2022-06)	2L; 1L (2024.01-2025.12)	64,145
befotertinib	贝福替尼	赛美纳	InventisBio, Beta Pharma (贝达药业)	2L (2023-05); 1L (2023-10)	2L (2024.01-2025.12)	77,285 (75mg/day)
rezivertinib	瑞齐替尼	瑞必达	Beta Pharma (倍而达药业)	2L (2024-05)	NA	-
oritinib	瑞厄替尼	圣瑞沙	Shenghe Pharma	2L (2024-06)	NA	-

Source: PharmCube, CMBIGM. Note: Data as of Aug 2024; Beta Pharma (贝达药业) will receive sales royalties from Beta Pharma (倍而达药业) on the sales of rezivertinib.

As of Aug 2024, six 3G EGFR-TKIs have been approved in China (refer to figure above). Osimertinib has been approved for 2L, 1L and adjuvant NSCLC treatment, covered by NRDL. Aumolertinib, similarly, has also been approved for 2L and 1L indications. Additionally, its sNDA for the adjuvant indication and Stage III maintenance therapy were submitted in Jul and Aug 2024, respectively. Furmonertinib is covered by the NRDL for both 2L and 1L indications. On the other

hand, befotertinib has yet to have its 1L indications covered by the NRDL, highlighting a disparity in reimbursement status among these therapies. This dynamic regulatory and reimbursement landscape continues to evolve.

Figure 12: Late clinical-stage 3G EGFR-TKIs

Drug name	Target	Company	China stage	US stage	Comments
兰泽替尼/lazertinib	EGFR T790M	J&J; Yuhan; Luoxin Pharma; Genosco	NDA	Approved	Approval of lazertinib + amivantamab for 1L NSCLC with EGFR ex19del or L858R based on MARIPOSA trial
Limertinib/ASK120 067	EGFR T790M;BTK;ITK	Beijing Aosaikang	NDA	-	
TY-9591	EGFR T790M	Boji Medical; TYK Medicines; Runnuo Biotech	Ph3	-	
YK-029A	EGFR T790M;EGFR exon 20	Puhe BioPharma	Ph3	-	
olafertinib	EGFR T790M	Checkpoint Therapeutics; Runnuo Biotech	Ph3	Ph1	
FHND9041	EGFR T790M	CTFH (SinoBiopharm)	Ph3	-	
诺司替尼/rociletinib	EGFR T790M	Clovis Oncology; BMS	Ph3	Ph3	Terminated
naquotinib	EGFR T790M	Astellas Pharma	Ph3	Ph3	Terminated
奥莫替尼/olmutinib	EGFR T790M	Hanmi; BI; ZaiLab	Ph2	Ph2	Terminated

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

Osimertinib is at the forefront of global EGFR-TKI development, boasting the most extensive range of approved indications among 3G EGFR-TKIs. It is actively involved in multiple Ph3 trials aimed at expanding its use to as early a treatment line as possible. In the Chinese market, major domestic EGFR-TKI players are primarily focused on 2L T790M+ NSCLC, 1L NSCLC with exon 19 deletions or L858R mutations, and adjuvant treatments, mirroring the approved indications of osimertinib.

Aumolertinib is maintaining a robust competitive stance in the EGFR-TKI market, spearheading multiple unique late-stage clinical trials to broaden its indications. Distinguishing itself from other domestic competitors but paralleling osimertinib, aumolertinib is engaged in Ph3 combination trials with chemotherapy for 1L NSCLC and with a cMET inhibitor for osimertinib-resistant MET+ patients. Meanwhile, furmonertinib is involved in Ph3 trials targeting the relatively uncommon exon 20 insertion mutations in 1L patients—a path not pursued by aumolertinib likely due to the smaller patient population in this segment and increasing market competitiveness.

Like osimertinib, aumolertinib is also undergoing a Ph3 trial for unresectable Stage III EGFRm NSCLC following chemoradiotherapy (CRT), with the sNDA under CDE review since Aug 2024. In Western markets, where the frequency of EGFR mutations is relatively lower, competition among 3G EGFR-TKIs is moderate, with osimertinib being the only marketed drug in this category, followed by the recent approval of J&J's lazertinib in Aug 2024 in combo with amivantamab for 1L NSCLC. Additionally, furmonertinib has been licensed to ArriVent for MRCT Ph3 development.

In the Chinese market, aumolertinib is maintaining a strong competitive position in the EGFR-TKI market, with several late-stage trials to broaden its indications to adjuvant therapies, maintenance therapies and combination therapies with various modalities. Aumolertinib will potentially become the first domestic EGFR-TKI approved for adjuvant EGFRm NSCLC with sNDA filed in Jul 2024, and also potentially the first domestic EGFR-TKI for maintenance therapy for Stage III EGFRm NSCLC after chemoradiation with sNDA submitted in Aug 2024. Furmonertinib, befotertinib and oritinib have Ph3 studies in adjuvant EGFRm NSCLC ongoing. In addition, aumolertinib was the first domestic EGFR-TKI which initiated the Ph3 study in 1L EGFRm NSCLC in combination with chemo. Moreover, aumolertinib is in Ph3 combination study with cMET inhibitors for osimertinib-resistant MET+ NSCLC patients.

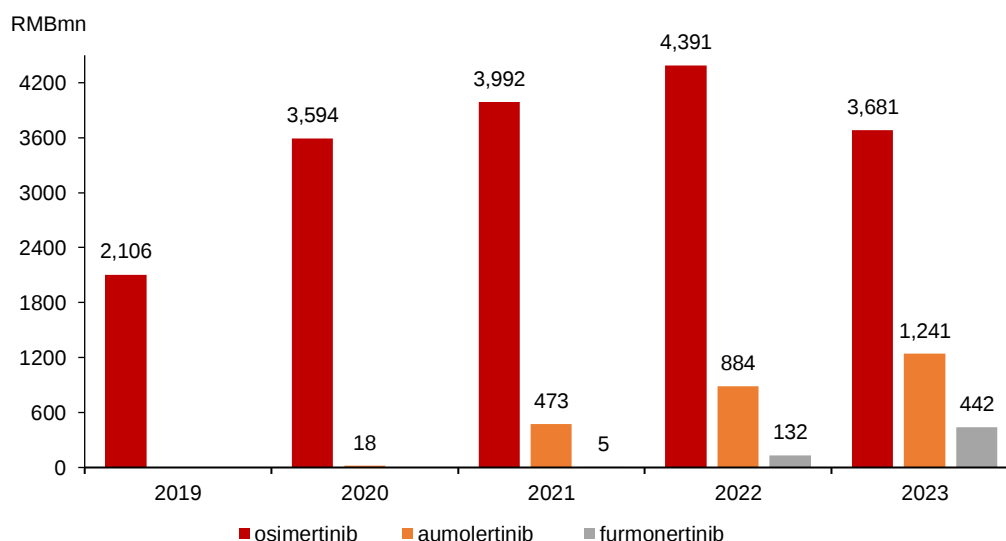
Figure 13: Ph3/pivotal trials of competing domestic 3G EGFR-TKIs

	Indication	Stage and ID	Regimen	Status
furmonertinib	Adjuvant Stage II-III A	Ph3, China, FORWARD	vs placebo	Started in 2021.04
	1L NSCLC (with rare mutation PACC or L861Q)	Ph3, China		IND approved in 2023.08
	1L NSCLC (with exon 19 deletions or exon 21 L858R)	Ph3, China, FURLONG	vs gefitinib	NDA approved
	1L NSCLC (with exon 20 insertion)	Ph3, Global (US, China, EU, etc), FURVENT	vs chemo	Overseas FPI in 1H23, partnering with ArriVent
	2L NSCLC (with exon 20 insertion)	Ph2, China, pivotal, NCT05466149	vs chemo	
	2L NSCLC (with T790M)	Ph2, China, pivotal, NCT03452592	single arm	NDA approved
	nsq-NSCLC with CNS metastatic	Ph3, China, CTR20242992	furmonertinib+chemo vs osimertinib	IND approved in Jul 2024
befotertinib	Adjuvant Stage IB-IIIB	Ph3, China, NCT06041776	vs icotinib (1 st -Gen TKI)	Started in 2023.03
	1L NSCLC (with exon 19 deletions or exon 21 L858R)	Ph2/3, China, NCT04206072	vs icotinib	NDA approved
	2L NSCLC (with T790M)	Ph2, China, pivotal, NCT03861156	single arm	NDA approved
rezivertinib	1L NSCLC with EGFRm except exon 20 insertion	Ph3, China, NCT03866499	vs gefitinib	NDA submitted in 2024.01
	2L NSCLC (with T790M)	Ph2b, China, NCT03812809	single arm	NDA approved
oritinib	1L NSCLC (with exon 19 deletions or exon 21 L858R)	Ph3, China, NCT04239833	vs gefitinib	Started in 2020.01
	Adjuvant Stage II-IIIB	Ph3, China, NCT06080776	vs placebo	Started in 2023.05
	2L NSCLC (with T790M)	Ph2, China, NCT03823807	single arm	NDA approved

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

In China, the major 3G EGFR-TKIs, namely osimertinib, aumolertinib and furmonertinib, have all been covered by the NRDL for 1L and 2L EGFRm NSCLC. According to the data from PharmCube, in terms of sales in sample hospitals, osimertinib maintained its market leading position in China with RMB3.68bn sales in FY23, much higher than that of aumolertinib's RMB1.24bn during the period.

Allist Pharma's furmonertinib could be a strong competitor. Sales of furmonertinib rose from RMB235.7mn in FY21 to RMB1.98bn in FY23. Allist Pharma recorded RMB743mn revenue in 1Q24, which was mostly contributed by sales of furmonertinib. Furmonertinib was covered by NRDL for 2L NSCLC since Jan 2022, and for 1L NSCLC since Mar 2023. Furmonertinib renewed its NRDL coverage with 7% price cut in Jan 2024 with the current NRDL period expires in end 2025. Betta Pharma's befotertinib was the fourth approved 3G EGFR-TKI in China, with 2L NSCLC indication included in the NRDL since Jan 2024. We think Hansoh's aumolertinib will gradually take market share in China's EGFR-TKI market thanks to its wide indication coverage and superior efficacy and safety profile.

Figure 14: Sample hospital sales of 3G EGFR-TKI in China

Source: PharmaCube, CMBIGM

Forecast risk-adjusted peak sales of aumolertinib to reach RMB8.2bn in 2030E

Approved for 1L EGFR-mutated NSCLC with NRDLC coverage as monotherapy, and with additional Ph3 trials ongoing in combination with chemotherapy and other innovative modalities, we anticipate that the majority of aumolertinib's sales will derive from the 1L NSCLC indication in the long term. By 2030, we project that the 1L NSCLC indication will generate sales of RMB6.2bn, accounting for approximately 75% of the drug's total risk-adjusted sales. We also expect aumolertinib to secure approval for adjuvant EGFR-mutated NSCLC treatment by mid-2025, which we believe could contribute RMB1.9bn in long-term peak sales. Overall, we foresee the peak sales of aumolertinib to reach RMB8.2bn by 2030E.

Figure 15: Sales forecast of aumolertinib

Aumolertinib sales projection									
	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Sales in adjuvant EGFRm NSCLC in China (RMB mn)	0	225	791	1,345	1,590	1,729	1,870	1,948	1,842
Probability of success in China	90%	90%	90%	90%	90%	90%	90%	90%	90%
Sales in 1L EGFRm NSCLC in China (RMB mn)	3,743	4,378	4,827	5,409	5,737	5,956	6,154	5,986	5,371
Probability of success in China	100%	100%	100%	100%	100%	100%	100%	100%	100%
Sales in 2L EGFRm NSCLC in China (RMB mn)	761	736	655	580	479	403	325	230	210
Probability of success in China	100%	100%	100%	100%	100%	100%	100%	100%	100%
Risk-adjusted China Sales (RMB mn)	4,504	5,316	6,194	7,200	7,648	7,914	8,162	7,969	7,239
NSCLC – China (patient number in 000)									
	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Total NSCLC cancer new cases in China	780	804	828	853	878	905	932	950	969
Total EGFRm NSCLC new cases in China	390	402	414	426	439	452	466	475	485
% EGFR mutated NSCLC	50%	50%	50%	50%	50%	50%	50%	50%	50%
Diagnosed incident stage III/IV NSCLC patients	254	262	269	278	286	294	303	309	316
% of NSCLC diagnosed incidence patient in stage III/ IV	65%	65%	65%	65%	65%	65%	65%	65%	65%
Diagnosed incident early stage NSCLC patients	136	140	144	149	153	158	163	166	169
% of NSCLC diagnosed incidence patient in early stage	35%	35%	35%	35%	35%	35%	35%	35%	35%
Annual cost of Aumolertinib (RMB)	73,500	69,825	62,843	61,586	60,354	59,147	57,964	56,805	53,964
% price change YoY		-5%	-10%	-2%	-2%	-2%	-2%	-2%	-5%
Adjuvant EGFRm NSCLC									
	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
EGFRm NSCLC patients receiving adjuvant therapy	7	18	30	37	41	46	50	55	56
Penetration of EGFR-TKI in adjuvant therapy for NSCLC	5%	13%	21%	25%	27%	29%	31%	33%	33%
Patients on Aumolertinib for adjuvant NSCLC	4	11	14	16	17	19	20	20	19
Volume share of Aumolertinib for adjuvant NSCLC		20%	35%	38%	38%	38%	38%	36%	34%
Sales from adjuvant NSCLC (hospital level, RMB mn)	255	896	1,524	1,802	1,959	2,118	2,207	2,087	2,087
Distributor markup		10%	10%	10%	10%	10%	10%	10%	10%
VAT		3%	3%	3%	3%	3%	3%	3%	3%
Sales from adjuvant NSCLC (exfactory, RMB mn)	225	791	1,345	1,590	1,729	1,870	1,948	1,948	1,842
1L EGFRm NSCLC									
	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Recurrent patient pool	82	84	87	89	92	95	98	99	101
% early stage recurrent rate	60%	60%	60%	60%	60%	60%	60%	60%	60%
Total drug treated 1L NSCLC EGFRm patients	302	311	320	330	340	350	361	368	375
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%	90%
EGFRm NSCLC patients on 3G EGFR-TKI 1L therapy	214	230	247	264	282	298	314	327	334
Penetration of 3G TKI in 1L therapy for EGFRm NSCLC	71%	74%	77%	80%	83%	85%	87%	89%	89%
Patients on Aumolertinib for 1L EGFRm NSCLC	41	51	62	69	73	77	82	79	73
Volume share of Aumolertinib for 1L EGFRm NSCLC	19%	22%	25%	26%	26%	26%	26%	24%	22%
Sales from 1L NSCLC (hospital level, RMB mn)	4,241	4,960	5,469	6,128	6,500	6,748	6,973	6,782	6,086
Distributor markup	10%	10%	10%	10%	10%	10%	10%	10%	10%
VAT	3%	3%	3%	3%	3%	3%	3%	3%	3%
Sales from 1L EGFRm NSCLC (exfactory, RMB mn)	3,743	4,378	4,827	5,409	5,737	5,956	6,154	5,986	5,371
2L EGFRm NSCLC									
	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
1L EGFRm NSCLC patients receiving 1/2G EGFR-TKI	73	65	58	50	41	35	29	22	23
% of 1L EGFRm NSCLC patients on 1/2G EGFR-TKI	24%	21%	18%	15%	12%	10%	8%	6%	6%
Patient post 1/2G EGFR-TKI	58	52	46	40	33	28	23	18	18
% of patients progressing with 1/2G EGFR-TKI	80%	80%	80%	80%	80%	80%	80%	80%	80%
1/2G TKI-post EGFRm NSCLC receiving 3G EGFR-TKI	40	37	34	30	25	21	18	14	14
% treatment rate	85%	85%	85%	85%	85%	85%	85%	85%	85%
Penetration of EGFR-TKI in 1/2G TKI-post EGFRm pts	82%	84%	86%	88%	90%	90%	90%	90%	90%
Patients on Aumolertinib for TKI-post EGFRm NSCLC	12	12	12	11	9	8	6	5	4
Volume share of Aumolertinib for TKI-post EGFRm NSCLC	29%	32%	35%	36%	36%	36%	36%	34%	32%
Sales from 2L EGFRm pts (hospital level, RMB mn)	862	834	742	657	543	456	369	261	238
Distributor markup	10%	10%	10%	10%	10%	10%	10%	10%	10%
VAT	3%	3%	3%	3%	3%	3%	3%	3%	3%
Sales from 2L EGFRm pts (exfactory, RMB mn)	761	736	655	580	479	403	325	230	210

Source: CMBIGM

Hengmu (tenofovir amibufenamide), targeting the sizable HBV market with improved safety profile

Sizable chronic hepatitis B market in China

Hengmu (tenofovir amibufenamide tablets / TMF, 艾米替诺福韦) is an innovative tenofovir prodrug internally developed by Hansoh, and is the first domestically developed oral dose innovative medicine indicated for chronic hepatitis B. The drug was approved in Jun 2021 and has been included in the NRDL since Jan 2022. The next round of NRDL renewal of Hengmu will be in end-2025. Hengmu is currently priced at RMB456 per month. We expect the pricing to remain largely stable.

Hengmu is a novel nucleotide reverse transcriptase inhibitor, which has higher cell membrane penetration rate and is easier to enter liver cells to achieve liver-targeting effect so that it can effectively improve drug plasma stability and reduce systematic exposure of tenofovir in patients. Consequently, Hengmu offers a safer and more effective option for long-term treatment.

There are around 86mn people with chronic hepatitis B virus (HBV) infection in China, in which 20-30mn people have hepatitis B. 15-40% chronic hepatitis B (CHB) patients could develop cirrhosis and hepatocellular carcinoma (HCC) in the long run, therefore actively treating CHB is required. However, the current diagnosis and treatment rate of CHB in China was just 22% and 15% ([link](#)), indicating large market potential. The guideline-recommended first-line options for chronic hepatitis are mainly nucleotide analogues drugs (NAs, [link](#)) to interfere viral replication, including Hengmu (TMF), Tenofovir disoproxil fumarate (TDF), Tenofovir alafenamide fumarate (TAF) and Entecavir (ETV), all of which have been covered by the NRDL.

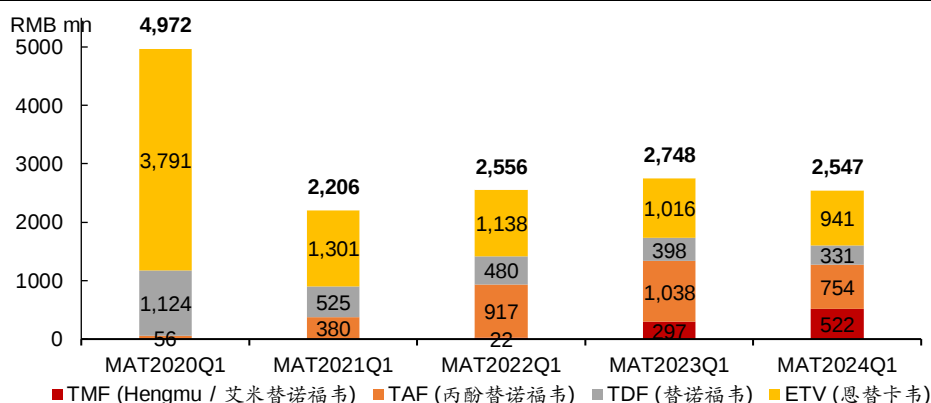
TDF, TAF and ETV were included in the national VBP, which caused sharp sales decline during recent years. We think Hengmu (TMF) will be free from VBP risk as an innovative drug with. Due to better safety profile of Hengmu, we think the drug will gradually gain market share in the sizable hepatitis B market.

Figure 16: Major chronic hepatitis B medicines in China

Drug name	Approval date in China	NRDL coverage	National VBP	Treatment cost
TMF (Hengmu / 艾米替诺福韦)	2021-06	Y	N	RMB456/month
TAF (丙酚替诺福韦)	2018-10	Y	VBP since 2022	RMB378/month (original drug) RMB11.7/month (generic drug, lowest in VBP)
TDF (替诺福韦)	2008-07	Y	VBP since 2018	RMB329/month (original drug) RMB8.7/month (generic drug, lowest in VBP)
ETV (恩替卡韦)	2005-11	Y	VBP since 2019	RMB607/month (original drug) RMB3.6/month (generic drug, lowest in VBP)

Source: PharmaCube, CMBIGM

Figure 17: Sample hospital sales of CHB medicines in China



Source: PharmaCube, CMBIGM. Note: VBP related price cut had a major impact to sales.

Improved safety of Hengmu to support market share gains

Hengmu (TMF) has demonstrated non-inferior efficacy than TDF in a head-to-head study, while Hengmu has better safety profile than TDF in terms of renal and bone side effects. The 96-week data of Hengmu (TMF) vs TDF in the Ph3 pivotal trial for chronic hepatitis B patients was published in end-2022 ([link](#)). The virological response rate was non-inferior between the TMF and TDF arms – in the HBeAg-positive population, 70.8% of patients in the TMF treatment group achieved HBV DNA <20 IU/mL, compared with 72.0% in the TDF treatment group (p=0.746); in the HBeAg-negative population, the proportions of HBV DNA <20 IU/mL were 93.9% and 93.3% in the TMF and TDF groups respectively (p=0.889). The ALT normalization rate in the TMF group was superior to that in the TDF group (74.4% vs 64.9%, p=0.002). Additionally, in cross-trial comparison, TMF's efficacy is comparable to that of TAF in terms of the virological suppression defined by HBV DNA levels.

The major safety concerns of the long-term use of TDF are renal toxicity and reductions of bone mineral density. Hengmu demonstrated better safety profile than TDF in terms of renal and bone side effects. For renal side effect, the decrease of creatinine clearance rate (CrCl-cg) was significantly smaller in the TMF group compared to TDF (-3.01 mL/min vs -6.65 mL/min, respectively, p<0.001), and a similar difference was seen for non-indexed estimated glomerular filtration rate (eGFR-epi, -1.68 mL/min vs -3.12 mL/min for TMF vs. TDF, p=0.010). For bone side effect, the patients receiving TMF had statistically lower decrease in bone mineral density in hip, femur neck and spine than the patients receiving TDF. However, TMF therapy seems to have a higher incidence of metabolism and nutrition disorder and hepatic steatosis than TDF therapy, while TDF treatment has a lipid or weight lowering effect. No significant differences in the incidences of cardiovascular diseases was observed between two treatment arms. Hengmu's superior safety profile support its market share gains, in our view.

Figure 18: Hengmu demonstrates superior safety profile over TDF, while efficacy on par with TAF

Drug name	Hengmu (tenofovir amibufenamide tablets)	Tenofovir alafenamide fumarate
Drug name abbr.	TMF	TAF
Trial ID	NCT03903796	NCT02836249, NCT02836236
Regimen	TMF vs TDF	TAF vs TDF
Follow-up	96 weeks	144 weeks
HBV DNA <20 IU/mL	HBeAg-positive pts: 70.8% vs 72.0%, p=0.746, noninferior HBeAg-negative pts: 93.9% vs 93.3%, p=0.889, noninferior	-
HBV DNA <29 IU/mL	HBeAg-positive pts: 74.7% vs 78.9%, p=0.204, noninferior HBeAg-negative pts: 94.4% vs 93.3%, p=0.748, noninferior	HBeAg-positive pts: 82.9% vs 78.9%, noninferior HBeAg-negative pts: 93.3% vs 92.0%, noninferior
ALT normalization rate	74.4% vs 64.9%, p=0.002	HBeAg-positive pts: 76% vs 67% HBeAg-negative pts: 80% vs 71%
grade≥3 TRAEs	6.3% vs 6.8%	<1% vs <1%
Change of creatinine clearance rate (mL/min)	-3.01 vs -6.65, p<0.001	-0.4 vs -3.2, p=0.014
Change of estimated glomerular filtration rate (mL/min)	-1.68 vs -3.12, p=0.010	+0.7 vs -3.7, p=0.0135
Bone mineral density in hip	-0.44% vs -2.47%, p<0.001	-0.95% vs -1.93%
Bone mineral density in spine	+0.04% vs -2.13%, p<0.001	+0.35% vs -1.40%
Source	Link	Link

Source: PharmaGo, CMBIGM

Saint Luolai (pegmolesatide), the only long-acting ESA for renal anemia

The only monthly-dosed ESA for renal anemia in China

Saint Luolai (pegmolesatide injection, 培莫沙肽), a synthetic peptide-based erythropoietin (EPO) receptor agonist, was approved in 2023 for treating renal anemia in chronic kidney disease (CKD) adult patients (1) who have not received erythropoiesis-stimulating agents (ESAs) and not on dialysis; and (2) who are receiving short-acting erythropoietin treatment and on dialysis.

Renal anemia is one of the most common complications of CKD. Anemia not only affects the quality of life of patients with kidney disease, but also promotes the progression of kidney disease and increases the risk of end-stage renal diseases, cardiovascular events, and death. The prevalence of CKD among Chinese adults is 10.8%, and more than 50% of them are anemic. With the progression of CKD, the prevalence of renal anemia continues to increase, and the overall anemia rate among non-dialysis CKD patients is 28.5%-72.0%, while the prevalence rate of anemia among dialysis patients is as high as 91.6%-98.2%. At present, it is estimated that there are around 1 million dialysis patients in China, and around 2 million non-dialysis CKD patients require treatment for renal anemia.

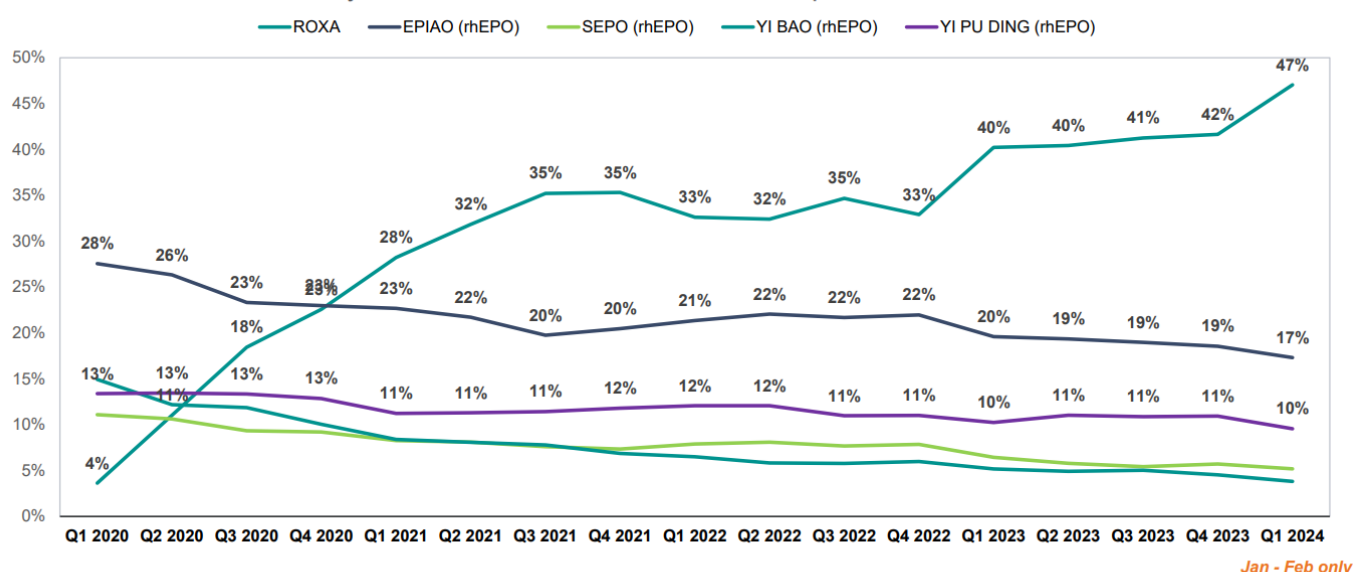
Insufficient production of erythropoietin (EPO, 红细胞生成素) is one of the major causes of renal anemia. According to the Chinese renal anemia treatment guideline ([link](#)), the adoption of erythropoiesis-stimulating agents (ESAs) to supplement EPO and the regulation of endogenous EPO through HIF-PHI (hypoxia-inducible factor prolyl hydroxylase inhibitor) are key therapies for renal anemia. ESAs are analogs of EPO and there are three generations of ESAs, including the first generation (1G) recombinant human rhEPOs (short-acting, administered every 1-3 times per week), the second generation (2G) darbepoetin alfa (达依泊汀 α, long-acting, administered every 1-2 weeks) and the third generation methoxy-polyethylene glycol-epoetin beta (CERA, long-acting, administered every 2-4 weeks). According to the guidelines, these three types of ESAs significantly decrease the necessity for blood transfusions and alleviate anemia-associated symptoms in CKD patients. Furthermore, in non-dialysis CKD patients, these three types of ESAs exhibit no significant differences in terms of elevating hemoglobin levels or causing adverse reactions. The selection of ESAs should be based on the patient's clinical status, tolerance, adherence, and variations in hemoglobin levels. Hansoh's Saint Luolai, approved in Jun 2023, is the only long-acting EPO administered monthly in China. It demonstrates superior efficacy and an enhanced safety profile.

HIF-PHI is a new class of orally-administered small molecule drugs designed for treating renal anemia. It regulates the body to stimulate red blood cell production by promoting endogenous physiological concentrations of EPO and receptor expression. Roxadustat (罗沙司他) and enarodustat (恩那度司他) have received approval both in China and globally for treating renal anemia. Roxadustat's patent in China expired in Jun 2024, while several generics have been approved in China and over 20 generics have filed ADNA. We think roxadustat will face fierce price competition.

The renal anemia market in China is primarily dominated by HIF-PHI inhibitor and the first generation of ESAs, accounting for around 85% of the market. According to the financial report of FibroGen, roxadustat recorded US\$284mn (+36% YoY) sales in FY23 in China with market share of over 40% ([link](#)), indicating China's renal anemia market size of US\$710mn (or RMB5.2bn) in 2023. In 1Q24, roxadustat's market share increased to 47% ([link](#)), followed by first generation ESAs such as EPIAO (益比奥, 17%), YI PU DING (依普定, 10%), SEPO (赛博尔) and YI BAO (怡宝). As reported by 3SBio, EPIAO and SEPO recorded RMB940mn revenue in FY23, capturing 42.2% share of the Chinese rhEPO market ([link](#)). Currently, short-acting recombinant human EPO is the primary ESA treatment for renal anemia in China, requiring 1-3 injections per week. However, the frequency of these injections often results in low patient compliance.

Figure 19: Market share split of major brands in the renal anemia market in China

Quarterly Brand Share based on \$ Sales - Top 5 of ESA+HIF Market



Source: IQVIA MIDAS, accessed Apr 7th, 2024. Notes: Market definition includes B3C0 Erythropoietin Products and B3D0 HIF-PH Inhibitors (ATC4), does not include iron. No indication split applied, i.e., includes ESA sales outside of CKD. Discrepancies between IQVIA MIDAS and company-reported sales (\$ and volume) are due to data capture limitations and 'volume to \$' conversion based on list price

Source: FibroGen's 1Q24 financial report, CMBIGM. Note: ROXA means roxadustat. Roxadustat's NDA in the US was rejected by FDA.

Saint Luolai (pegmolesatide) is an EPO mimetic peptide that has been modified with a third-generation branched polyethylene glycol. This modification significantly extends its half-life and reduces its immunogenicity. Pegmolesatide holds the distinction of being the only EPO mimetic peptide approved in the world and the sole monthly EPO in China. Administered subcutaneously on a monthly basis, pegmolesatide substantially reduces the administration frequency, bringing it down from a potential maximum of 156 annual injections to just 13.

What makes pegmolesatide unique is its lack of amino acid sequence homology with EPO, which means it does not induce anti-EPO antibody production or cause pure red blood cell aplasia (PRCA, 纯红细胞再生障碍性贫血), a rare but serious condition where the body fails to produce new red blood cells. The EPO receptor has a high affinity and specificity for pegmolesatide, allowing it to continuously and stably stimulate erythropoiesis (red blood cell production) while maintaining a strong safety profile.

Competitive profile of pegmolesatide to support market share gains

Pegmolesatide has showcased superior efficacy compared to first-generation rhEPO. Hansoh has successfully completed two non-inferiority Ph3 trials comparing pegmolesatide and epoetin alfa (利血宝/依泊汀 α, 1G ESA) ([link](#)) in both on-dialysis and non-dialysis CKD patients. In the specific case of CKD patients undergoing dialysis, a non-inferiority Ph3 trial (HS-20039-302, n=372) was conducted in China ([link](#)), comparing pegmolesatide with epoetin alfa. The pegmolesatide group (n=233) saw a mean change in hemoglobin level from the baseline of +0.076g/dL, while the epoetin alfa group (n=114) experienced a change of -0.224g/dL. The between-group difference was 0.297g/dL (95% CI 0.11–0.47, p=0.0011), which not only confirmed the primary endpoint of pegmolesatide's non-inferiority to epoetin alfa but also demonstrated its superiority in efficacy.

Figure 20: Pegmolesatide's efficacy vs 1G rhEPO in CKD patients on dialysis

	pegmolesatide study (FAS)		roxadustat study (FAS)	
	pegmolesatide	epoetin alfa	roxadustat	epoetin alfa
Follow up	17-24 weeks		23-27 weeks	
Baseline (g/dL)	11.110	11.114	10.42	10.47
Hb change vs baseline (g/dL)	0.076	-0.224	0.73	0.46
Hb at evaluation (g/dL)	11.186	10.890	11.19	10.93
Difference (g/dL)	0.297 (p=0.0011)		0.22 (p=0.0718)	

Source: drug label, CMBIGM

For non-dialysis CKD patients, in the Ph3 trial (HS-20039-301, n=175), the mean change in hemoglobin level from baseline was 1.933g/dL in the pegmolesatide group and 1.516g/dL in the epoetin alfa group. The between-group difference was 0.378g/dL (p=0.0163). These results not only confirmed the primary endpoint of non-inferiority of pegmolesatide to epoetin alfa but also demonstrated its superior efficacy.

Figure 21: Pegmolesatide's efficacy vs 1G rhEPO in non-dialysis CKD patients

	pegmolesatide study (FAS)		roxadustat study (FAS)	
	pegmolesatide	epoetin alfa	roxadustat	epoetin alfa
Follow up	17-24 weeks		7-9 weeks	
Baseline (g/dL)	8.902	8.969	8.87	8.93
Hb change vs baseline (g/dL)	1.933	1.516	1.9	-0.4
Hb at evaluation (g/dL)	10.834	10.486	10.77	8.53
Difference (g/dL)	0.378 (p=0.0163)		/	

Source: Drug label, CMBIGM

Pegmolesatide has not only shown exceptional efficacy but also a superior safety profile compared to epoetin alfa and other competing products. The incidences of hypertensive adverse reactions, composite safety events, all-cause mortality, and other cardiovascular events were significantly lower than its peers. It is worth noting that while roxadustat was approved in China for renal anemia in 2018, the US FDA rejected its NDA in 2021 due to safety concerns, including an increased incidence of thrombosis, seizures, major infections, and even a higher mortality rate.

Figure 22: Pegmolesatide's strong safety profile

	Dialysis indication			Non-dialysis indication		
	pegmolesatide	epoetin alfa	roxadustat	pegmolesatide	epoetin alfa	roxadustat
Hypertension adverse reaction	4.9%	6.5%	4.4%	0.9%	1.7%	1.0%
Composite safety events /MACE (all-cause mortality, stroke, myocardial infarction)	2.4%	4.0%	15.8%	0.9%	3.4%	20.0%
All-cause mortality	1.6%	3.2%	10.7%	0.9%	3.4%	16.8%
Other cardiovascular events	1.2%	4.0%	3.5%	0.0%	5.2%	4.1%
Thromboembolic events (血栓栓塞事件)	4.9%	Vascular pathway thrombosis 10.5%; Deep vein thrombosis 1.0%	Vascular pathway thrombosis 13.0%; Deep vein thrombosis 1.5%	1.7%	/	Vascular pathway thrombosis 2.8%; Deep vein thrombosis 1.2%

Source: Drug label, CMBIGM

From an efficacy standpoint, separate studies have shown that pegmolesatide exhibits superior hemoglobin increase compared to first-generation ESAs, whereas roxadustat demonstrated a non-inferiority profile to ESAs. Pegmolesatide also showcased better tolerability. These factors underscore the competitiveness of pegmolesatide in terms of both hemoglobin level improvement and safety.

Pegmolesatide, approved in China in Jun 2023, has been included in the NRDL since Jan 2024, leading to a 61% reduction in its price and thus improving affordability for patients. For dialysis and non-dialysis CKD patients, the

treatment cost is approximately RMB1,375 and RMB779 per month, lower than that of roxadustat and higher than first-generation rhEPOs.

Figure 23: Cost estimate of major drugs for renal anemia

Drug	Cost estimate (based on 60kg weight)	NRDL	Dose interval
roxadustat (罗沙司他)	Dialysis pts: RMB1,504/month Non-dialysis pts: RMB1,205/month	2024.01-2025.12	3 times per week, orally
pegmolesatide	Dialysis pts: 1,375/month Non-dialysis pts: RMB779/month	2024.01-2025.12	Monthly, subcutaneous
EPIAO (rhEPO, 益比奥)	Dialysis pts: RMB611/month Non-dialysis pts: RMB407/month	Regular list	2-3 times per week, subcutaneous or intravenous

Source: PharmCube, CMBIGM. Note: As of Aug 2024

We think both short-acting rhEPO and roxadustat will face pricing pressure due to fierce competition. With largely stable pricing, we anticipate pegmolesatide, with its competitive efficacy and safety profiles and affordability coverage under the NRDL, to capture considerable market share in the Chinese renal anemia market.

Hansoh Xinfu (flumatinib), one of the mainstream BCR-ABL TKIs

Stable BCR-ABL TKI market with future market growth driven by newest generation TKIs

Hansoh Xinfu (flumatinib, 氟马替尼), a second generation BCR-ABL TKI, was approved in Nov 2019 for the treatment of philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in adult patients in the chronic phase.

CML is a type of cancer of the bone marrow, which starts in the blood-forming cells of the bone marrow and invades the blood, causing an increased number of white blood cells in the blood. About 15-20% of leukemias in adults are CML. CML cells contain an abnormal gene, BCR-ABL, forming with the ABL gene from chromosome 9 joining to the BCR gene on chromosome 22. The changed chromosome 22 with the fusion gene on it is called the Philadelphia chromosome (Ph+), which is founded in around 95% of patients with CML, and in some people with ALL or AML. Depending on the phase of disease (chronic, accelerated, or blast phase), TKIs targeting BCR-ABL are the common treatment for CML. For chronic phase CML (CML-CP), which accounts for more than 85% of CML patients when the disease occurs, TKIs targeting BCR-ABL are the standard treatment. CML patients usually survive for a long time with 10-year survival rate of 80-90% with first generation BCR-ABL TKI imatinib's 1L treatment of CML-CP, indicating the long duration of treatment of BCR-ABL TKIs.

There are three generations of BCR-ABL TKIs globally, including the 1st generation (1G) imatinib, the 2nd generation (2G) dasatinib, nilotinib, flumatinib, bosutinib and the 3rd generation (3G) ponatinib and olverembatinib. The 1/2G TKIs imatinib, nilotinib, flumatinib and dasatinib are recommended by CSCO guideline for first-line CML-CP treatment. Almost all CML patients respond to treatment with first line BCR-ABL TKIs, and most of these responses last for many years. Each TKI has its own risk-benefit profile and if the first drug stops working due to resistance or it never worked, the dose may be increased or another TKI might be tried. Ponatinib or olverembatinib, usually used in later-line, are the options after all of the other TKIs have been tried or if the leukemia cells later develop the T315I mutation.

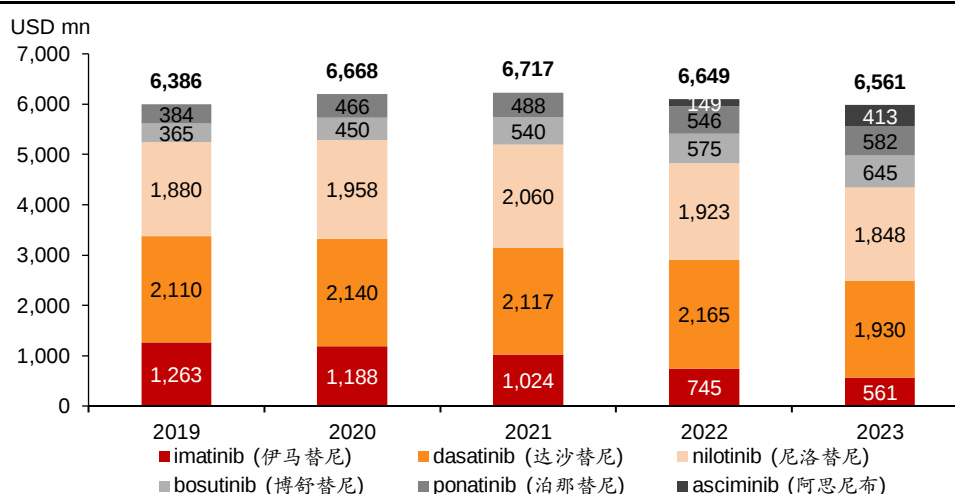
Figure 24: Three generations of BCR-ABL TKI options for CML

Generation	Drug name	Company	NRDL	VBP	Initial approval date	Approved indications
1G BCR-ABL TKI	imatinib (伊马替尼)	Novartis	Y	Y	2001 (US), 2005 (China)	CML, GIST, ALL, MDS, etc.
	dasatinib (达沙替尼)	BMS, Otsuka	Y	N, 5 generics	2006 (US), 2011 (China)	CML, ALL
2G BCR-ABL TKIs	nilotinib (尼洛替尼)	Novartis, KeifeRx	Y	N, 2 generics	2007 (US), 2009 (China)	CML
	flumatinib (氟马替尼)	Hansoh	Y (2023.03-2024.12)	N	2019 (China)	CML
	bosutinib (博舒替尼)	Pfizer	-	-	2012 (US)	CML
3G BCR-ABL TKIs	ponatinib (泊那替尼)	Takeda, Otsuka, Incyte	-	-	2012 (US)	CML (3L+ CP CML, T315I-positive CML, 1L AP/BP CML), Ph+ ALL (1L, T315I-positive)
	olverembatinib (奥雷巴替尼)	Ascentage, Innovent, Takeda	Y (2023.03-2024.12, limited to CML with T315I mutation)	N	2019 (China) 2L+ indication approved in Nov 2023	CML (T315I mutation, 2L+)
STAMP inhibitor	asciminib (阿思尼布)	Novartis	-	-	2021 (US)	CML (3L+, T315I mutation)

Source: PharmaGo, CMBIGM. Note: STAMP inhibitor means BCR::ABL1 inhibitor that specifically Targets the ABL Myristoyl Pocket (STAMP). Data as of Aug 2024.

For patients with Chronic Myeloid Leukemia in the accelerated phase (CML-AP), the treatment options are similar to those for the chronic phase. However, patients with CML-AP are less likely to have a long-term response to any treatment. In the blast phase of CML (CML-BP), the leukemia cells become more abnormal, often behaving like Acute Myeloid Leukemia (AML) cells. In these cases, TKIs may be beneficial for a smaller number of people and for shorter durations, particularly for individuals with CML-BP who have not received prior treatment.

Over the past few years, the global BCR-ABL TKI market size has remained relatively stable at around US\$6.6bn. This is mainly due to the patent expiration of certain first and second generation TKIs, including imatinib, dasatinib, and nilotinib. In China, imatinib was included in the Volume-Based Procurement (VBP). The global usage of imatinib has decreased over time since numerous studies show that second-generation TKIs are significantly more effective than imatinib in achieving complete cytogenetic response (CCyR) and major molecular response (MMR). Meanwhile, new generation TKIs, i.e. bosutinib, ponatinib and asciminib, which are approved in the US market while not in China yet, are continuing their market share gains.

Figure 25: Global sales of major BCR-ABL TKIs

Source: PharmCube, CMBIGM

Olverembatinib from Ascentage was approved in China in 2019 as the first marketed 3G BCR-ABL inhibitor and the only drug to treat TKI-resistant CML patients with T315I mutations, with the indication included in the NRDL already. In late

2023, olverembatinib was further approved for 2L+ treatment of chronic phase CML who are resistant to and/or intolerant of 1/2G TKIs. However, we do not expect olverembatinib will compete directly with Hansoh's flumatinib, as flumatinib is used in front-line, while olverembatinib's usage is limited to TKI pre-treated patients. Ascentage recently entered into an option agreement with Takeda regarding the ex-China rights of olverembatinib.

Asciminib from Novartis was approved in the global market (ex-China) for the 3L+ treatment of Ph+ CML-CP pre-treated with two or more TKIs, and patients with T315I mutations. For newly diagnosed CML, in a head-to-head Ph3 ASC4FIRST study ([link](#)), scemblix (asciminib) demonstrated superior MMR rates at week 48 vs investigator-selected SoC TKIs (imatinib, nilotinib, dasatinib and bosutinib) (67.7% vs 49.0%) and imatinib alone (69.3% vs 40.2%). Scemblix also demonstrated a favorable safety and tolerability profile vs imatinib and 2G TKIs, with fewer grade ≥ 3 AEs, dose adjustments, and half the rate of AEs leading to treatment discontinuation.

Asciminib recorded strong sales growth momentum with FY23 sales reaching US\$413m (+177% YoY) and 1Q24 sales increasing 83% YoY to US\$136mn, driven by demand in 3L+ CML. We expect asciminib to take meaningful market share in the global CML market.

Asciminib's NDA has been under review by the NMPA in China for CML since Jun 2024. Given asciminib's superior profile for first-line CML treatment compared to other first and second-generation TKIs, we anticipate that it will become a strong competitor in the Chinese BCR-ABL TKI market upon its approval, assuming appropriate pricing and good NRDL coverage.

Hansoh licensed in the Great China rights of HS-10382/TERN-701 from Terns Pharma in 2020. HS-10382 has the same MoA as asciminib and is currently under Ph1 development ([link](#)). HS-10382 binds to an allosteric pocket unique to the mutant BCR-ABL. Its high selectivity towards a target that is distinct from those of currently available BCR-ABL TKIs could potentially enhance efficacy and overcome acquired resistance that is difficult to treat.

Figure 26: Clinical data comparison of major BCR-ABL TKIs

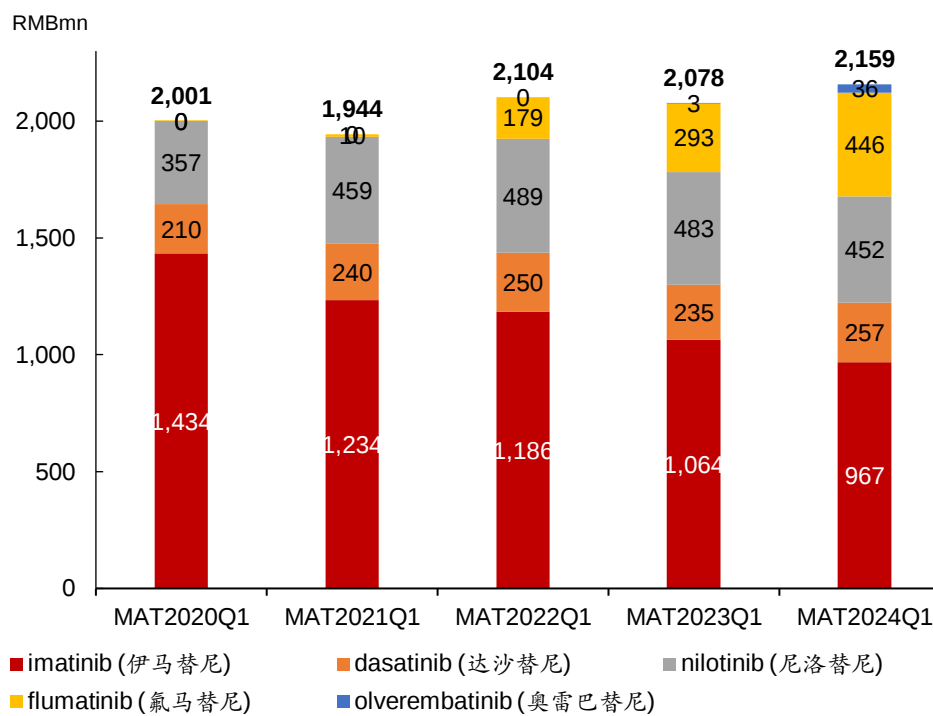
Medicine	flumatinib	nilotinib	dasatinib	asciminib
Regimen	flumatinib vs imatinib	nilotinib 300mg or 400mg vs imatinib	dasatinib vs imatinib	asciminib vs imatinib or asciminib vs 2G TKIs (nilotinib, dasatinib and bosutinib)
Trial ID	NCT02204644	NCT00471497	NCT00481247	NCT04971226
Patients no.	394	846	519	405
MMR at 12 months	52.6% vs 39.6%	44% or 43% vs 22%	46% vs 28%	69.3% vs 40.2% (imatinib) or 57.8% (2G TKIs)
CCyR at 12 months	91.4% vs 79.3%	80% or 78% vs 65%	77% vs 66%	-
AEs leading to discontinuation	10.2% vs 6.1%	5% or 9% vs 7%	5.0% vs 4.3%	asciminib vs imatinib vs 2G TKIs: 5% vs 11% vs 10%
Source	Link	Link	Link	Link

Source: Company data, CMBIGM

Flumatinib continues to be a mainstream 2G BCR-ABL TKI in China

In China, imatinib has been included in the VBP in China since 2018, and several generics of 2G TKIs have been approved in China. According to sample hospital sales data from PharmCube, the market size of the imatinib, dasatinib and nilotinib are shrinking. Such trend is driven by the implementation of the VBP for imatinib and intensified competition from generics of dasatinib and nilotinib.

We think flumatinib will maintain exclusive position in Chinese market in coming years. We anticipate that flumatinib will undergo a renewal process with the NRDL towards the end of 2024, which we expect will result in largely stable pricing for the drug.

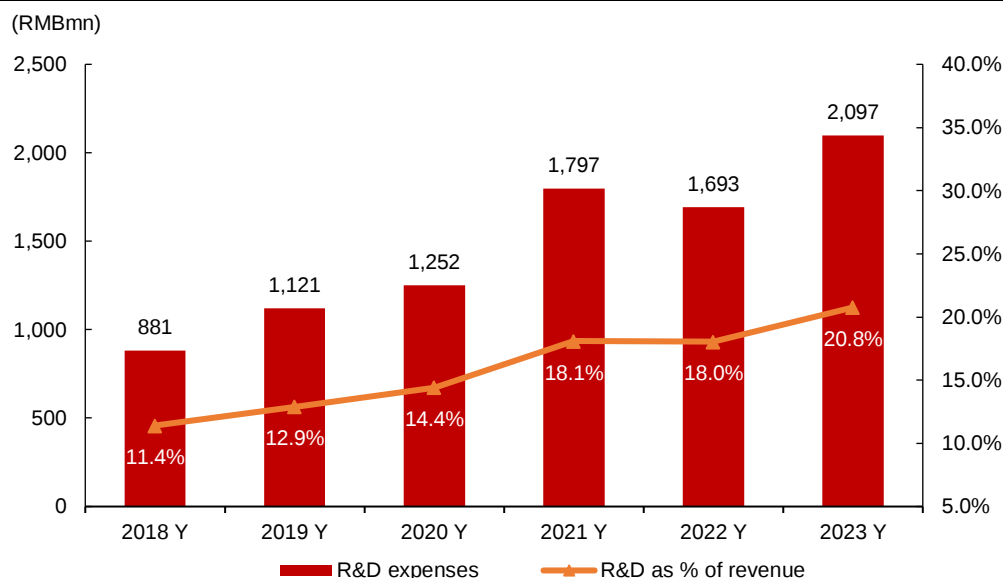
Figure 27: China's sample hospital sales of BCR-ABL TKIs


Source: PharmaGo, CMBIGM.

Continuous R&D efforts to expand innovative drug pipeline

Hansoh has demonstrated a consistent commitment to increase its investments in R&D over the years. The Company's annual R&D costs have grown at a 18.9% CAGR from RMB881mn in FY18 to RMB2,097mn in FY23. The R&D expenses to revenue ratio has also witnessed a substantial rise, from 11.4% in FY18 to 20.8% in FY23.

Figure 28: R&D expenses increased continuously



Source: Company data, CMBIGM

As of end-2023, Hansoh's R&D team comprised approximately 1,671 research fellows located at four R&D centers in Shanghai, Lianyungang, Guangzhou, as well as Maryland, the US. At end-2023, the Company had more than 50 clinical trials ongoing for its innovative drugs, covering over 30 innovative drug products. Hansoh aims to bring 8-10 new molecules to clinical stage of development every year, further expanding its innovative product pipelines.

Hansoh continues to expand the indication coverage of Ameile in adjuvant NSCLC, Stage III maintenance therapy, in combo with chemo in 1L NSCLC, or in combo with c-MET TKI and other innovative therapies. Additionally, we see the great potential of the Company's ADC assets, GLP-1 assets, TYK2 inhibitor, along with others.

The Company's ADC assets have gained recognitions from global MNC. In late 2023, the Company entered into agreements with GSK for the ex-China rights of its two ADC assets: HS-20093 (B7-H3 ADC) and HS-20089 (B7-H4 ADC). GSK has registered Ph1 trials for these two assets. Hansoh is actively developing HS-20093 (B7-H3 ADC) for multiple solid tumors in China, including a Ph3 trial in 2L ES-SCLC, a Ph3 trial in LS-SCLC, and multiple Ph2 trials in head and neck cancers, mCRPC, sarcoma and others. We see the BIC potential of HS-20093 in ES-SCLC and other solid tumor indications. HS-20089 (B7-H4 ADC) is undergoing Ph2 studies for the treatment of ovarian cancer and endometrial cancer in China, with FIC/BIC potential. Furthermore, Hansoh has in-licensed the China rights of an EGFR/cMET bsAb (HS-20117) from Biotheus (普米斯) and is developing an EGFR/cMET ADC (HS-20122) based on the bsAb with global rights. Hansoh has started a Ph2/3 study of HS-20117 in May 2024 and plans to initiate first-in-human studies of HS-20122 by end-2024.

In the GLP-1 franchise, Hansoh's Fulaimei (PEGylated loxenatide, GLP-1) launched in May 2019 was the first domestic innovative weekly GLP-1 hypoglycemic drug for the treatment of Type 2 diabetes. The Company is also developing a new-generation weekly-administered GLP-1/GIP dual agonist (HS-20094). Hansoh is evaluating HS-20094 in Ph2 trials for diabetes and obesity in China and plans to initiate Ph3 studies for obesity in 2H24. Additionally, Hansoh's HS-10501, an innovative oral GLP-1 drug, is currently in Ph1a stage.

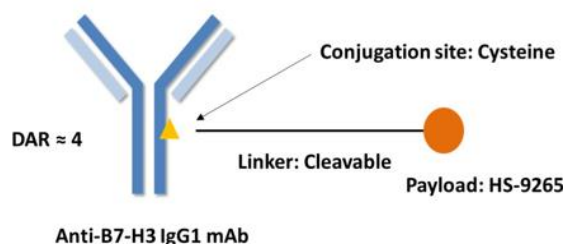
Figure 29: Hansoh's innovative drug pipeline

TA	Candidate	Target/MOA	Indications		Ph1	Ph2/POC	Ph 3/Pivotal	Registered
Oncology	Aumolertinib(Aumo)	3 rd -Gen EGFR	Adjuvant NSCLC					
			Chemo Combo NSCLC					
			Stage IIIB NSCLC					
			Non-canonical mutations NSCLC					
	HS-10241+Aumo	c-MET+ 3 rd -Gen EGFR	2L+cMET amplification+EGFRm NSCLC					
	HS-10365	RET	NSCLC					
			Thyroid cancer					
	HS-20093	B7-H3, ADC	2L+ SCLC					
			2L+Osteosarcoma/soft tissue sarcoma					
			2L+ CRPC					
			2L+ HNSCC					
			2L+ NSCLC					
			2L+ ESCC					
			other Solid Tumor					
	HS-20089	B7-H4, ADC	OC and Endometrial cancer					
			TNBC etc					
	HS-20106 ²	ActRIIA ligand trap	MDS, MF					
	HS-10502	PARP1	Breast Cancer etc					
	HS-10352	PIK3α	Breast Cancer etc					
Metabolic Disease and others	HS-10370	KRAS	Solid Tumor					
	HS-10382	Allosteric BCR-ABL	CML					
	HS-10502	PARP1	Breast Cancer etc					
	HS-10516	HIF2α	RCC and VHL and others					
	HS-20117	EGFR/c-met	NSCLC					
	HS-20122 Kiomedine TM One ⁴	EGFR/cMET ADC Chitosan	NSCLC					
			Knee osteoarthritis					
	HS-20094	GIP/GLP-1R agonist	T2D (+/- overweight)					
			Overweight					
	HS-10501	Oral GLP-1R	T2D or overweight					
	HS-10383	P2X3	Chronic cough					
	HS-10384	NK3	Menopausal Vasomotor Symptoms					
	HS-10518	GnRH	Endometriosis and others					
Auto-Immune and Renal Disease	Inebilizumab	CD19	IgG4 Related Disease					
			gMg					
	HS-10374	TYK2	Psoriasis					
			Psoriatic Arthritis					
CNS	HS-10390	ETA/AT1	FSGS、IgA nephropathy					
	HS-10398	Undisclosed	IgA nephropathy					
	HS-10353	GABAA Modulator	MDD					
			PPD					
	HS-10380	D3、D2/5-HT2A	Schizophrenia					
Anti Infective Disease	HS-10506	Undisclosed	Depression, insomnia					
	HS-10366	Glucan synthase	aVVC					
		Glucan synthase	Step-down treatment for IC					

Source: Company slides, CMBIGM. Note: As of Apr 2024

HS-20093 (B7-H3 ADC), broad indication potential, especially in SCLC

HS-20093 is a B7-H3 ADC, composed of a fully humanized anti-B7-H3 monoclonal antibody covalently linked to topoisomerase inhibitor (TOPOi) payload. B7-H3, also known as CD276, is a member of the B7 family overexpressed in tumor tissues, while showing limited expression in normal tissues. The overexpression of B7-H3 is often correlated with worse survival. B7-H3 has been extensively studied in various cancers, including but not limited to breast cancer, lung cancer, ovarian cancer, brain tumor, gastric cancer, and squamous cell carcinoma. B7-H3 ADC has potential to combine with other immune checkpoint inhibitors.

Figure 30: Structure of HS-20093

Source: Company data, CMBIGM.

Figure 31: Expression and diverse roles of B7-H3 in multiple types of human cancers

Cancer type	Case number	Positive rate	Cell category	Function
Breast cancer	74	57%	Cancer tissue	B7-H3 participated in the occurrence and metastasis of breast cancer
	74	43%	Adjacent tissue	
Non-small cell lung cancer	82	74%	Tumor samples	B7-H3 impaired anti-PD-1 therapy in NSCLC
Ovarian cancer	103	93%	Tumor samples	B7-H3 downregulated T cell mediated antitumor immunity
Meningioma	21	76%	Tumor cells	B7-H3 expression was elevated in patients with gene mutations related to the PI3K/AKT/mTOR pathway
	8	75%	Tumor tissue	B7-H3 protein might play important roles in meningioma immune responses
Gastric cancer	120	69%	Cancer tissue	B7-H3 silencing downregulates CXCR4
Esophageal squamous cell carcinoma	66	70%	Cancer tissue	Knockdown of B7-H3 on tumor cells suppressed ESCC cell migration and invasion
Cutaneous squamous cell carcinoma	66	85%	Tumor tissue	B7-H3 expression was the only parameter in immunocompetent individuals that was significantly different from that in immunosuppressed patients

Source: PubMed (link), CMBIGM

Hansoh is conducting multiple Ph2 studies of HS-20093 in China for the treatment of ES-SCLC, head and neck cancers, mCRPC, sarcoma and other solid tumors, and has registered a Ph3 trial of HS-20093 vs topotecan in 2L relapsed SCLC, and a Ph3 trial of HS-20093 vs active surveillance in limited-stage SCLC. HS-20093 recently received BTB designation from the FDA.

Figure 32: Clinical trials of HS-20093 (B7-H3 ADC) conducted by Hansoh

Trial ID	Regimen	Indication	Stage	Start date	Completion date	Patient number
NCT06526624/ ARTEMIS-009	mono vs active surveillance without intervention	Limited-stage SCLC (for pts have not progressed after chemoradio (CTR))	Ph3, PFS and OS endpoints	2024-09-30 (estimate)	2029-01-31	406
NCT06498479/ ARTEMIS-008	mono vs topotecan	2L SCLC (limited or extensive)	Ph3, OS endpoint	2024-07-15 (estimate)	2026-09-30	460
NCT06052423/ ARTEMIS-007	mono	1L ES-SCLC	Ph2	2024-11-30 (estimate)	2027-06-30	50
NCT06007729/ ARTEMIS-006	mono	HNSCC and other solid tumors	Ph2	2023-08-23	2027-12-12	170
NCT06112704/ ARTEMIS-005	mono	Esophageal carcinoma	Ph2	2023-11-01	2026-12-31	220
NCT06001255/ ARTEMIS-003	mono	mCRPC (2L+)	Ph2	2023-08-21	2025-12-31	120
NCT05830123/ ARTEMIS-002	mono	R/R osteosarcoma and other sarcomas	Ph2	2023-04-26	2027-12-31	170
NCT06332170/ ARTEMIS-101	+ adebrelimab (PD-L1) +/- chemo; + cetuximab +/- chemo; + enzalutamide (AR inhibitor)	Solid tumors	Ph1	2024-03-27	2028-05-30	610
NCT05276609/ ARTEMIS-001	mono	Solid tumors	Ph1	2022-03-11	2023-12-31	177

Source: PubMed, CMBIGM. Note: As of Aug 2024

In Dec 2023, Hansoh granted the ex-China rights of HS-20093 to GSK. GSK agreed to pay US\$185mn upfront fee and up to US\$1.525bn milestone payment. GSK will also pay tiered royalties on global net sales of HS-20093 outside of

China's mainland, Hong Kong, Macau, and Taiwan. GSK has registered a Ph1 MRCT study of HS-20093 (NCT06551142).

I-DXd and HS-20093 are leading the global B7-H3 ADC development

I-DXd and HS-20093, as Ph3-stage leading B7-H3 ADCs, have reported promising preliminary clinical results, demonstrating promising efficacy in SCLC. Globally, MacroGenics, BioNtech, MediLink, Mabwell Bioscience, Innovent, and Minghui Pharma also have B7-H3 ADCs at Ph2 stage.

MacroGenics' B7-H3 ADC MGC018 (or vobra duo) uses the prodrug seco-DUocarmycin hydroxyBenzamide Azaindole (DUBA) as payload, with a DAR of ~2.7. DUBA is an alkylating agent that can damage DNA in both dividing and non-dividing cells, causing cell death. MacroGenics released the updated results of the TAMARACK Ph2 study of MGC018 in mCRPC in May 2024 ([link](#)). Although MGC018 demonstrated satisfying efficacy in mCRPC, safety became a major concern given the five fatal events occurred in the Ph2 study.

Based on the updated risk-benefit data of the Ph2 trial including the primary endpoint of 6-month rPFS rate and updated safety, MacroGenics has decided to discontinue further dosing for the TAMARACK mCRPC study following IDMC's recommendation ([link](#)), while will continue to monitor for the patients. Detailed data will be presented at the ESMO meeting in Sep this year, with mature efficacy findings expected later in 2H24. MacroGenics is developing another B7-H3 ADC, MGC026, in Ph1 study, which uses exatecan, a topoisomerase I inhibitor, as payload.

Figure 33: Global development of B7-H3 ADCs

Drug name	Target	Action	Institute	Global phase	CN phase	US phase
I-DXd; ifinatamab deruxtecan; DS-7300a; MK-2400	Top I;B7-H3	anti-B7-H3 ADC; camptothecin; Top I inhibitor	Merck & Co.; Daiichi Sankyo	PhIII	PhIII	PhIII
HS-20093	Top I;B7-H3	anti-B7-H3 ADC; Top inhibitor	GSK; Hansoh	PhIII	PhIII	PhI
MGC018; vobramitamab duocarmazine	Top II;DNA; B7-H3	anti-B7-H3 ADC; anthracycline antibiotic; Top II inhibitor; DNA intercalator	MacroGenics	PhII	N/A	PhII
YL201	Top I;B7-H3	anti-B7-H3 ADC; camptothecin; Top I inhibitor	MediLink Therapeutics	PhII	PhII	PhI
7MW3711	Top I;B7-H3	anti-B7-H3 ADC; Top I inhibitor	Mabwell Bioscience	PhI/II	PhI/II	IND
DB-1311;BNT324	Top I;B7-H3	anti-B7-H3 ADC; Top I inhibitor	BioNTech; DualityBio	PhI/II	PhI/II	PhI/II
IBI129	B7-H3	anti-B7-H3 ADC	Innovent	PhI/II	PhI/II	N/A
IBI3001	EGFR;B7-H3	anti-B7-H3/EGFR ADC; anti-B7-H3/EGFR bispecific antibody	Innovent	PhI/II (Australia)	N/A	N/A
MHB088C	Top I;B7-H3	anti-B7-H3 ADC; Top I inhibitor	Minghui Pharma	PhI/II	PhI/II	N/A
BAT8009	Top I;B7-H3	anti-B7-H3 ADC; camptothecin; Top I inhibitor	Bio-Thera Solutions	PhI	PhI	N/A
MGC026	Top;B7-H3	anti-B7-H3 ADC; Top inhibitor	MacroGenics	PhI	N/A	PhI
BGB-C354	Top I;B7-H3	anti-B7-H3 ADC; Top I inhibitor	BeiGene	PhI	N/A	N/A
mirzotamab clezutoclast;ABBV-155	Bcl-xl;B7-H3	anti-B7-H3 ADC; Bcl-xl inhibitor	AbbVie	PhI	PhI	PhI

Source: PharmCube, CMBIGM. Note: Data as of Aug 2024. MacroGenics' MGC018 reported updated Ph2 data with five deaths, two of which were not drug-related, while the other three cases were still under investigation ([link](#)).

I-DXd (Ifinatamab deruxtecan) is a B7-H3 ADC developed Daiichi Sankyo. In Oct 2023, Merck in-licensed the ex-Japan rights of I-DXd. Daiichi is evaluating I-DXd monotherapy vs chemo for the treatment of 2L SCLC in a global Ph3 trial (IDeate-Lung02 study), and I-DXd monotherapy for pre-treated ES-SCLC in a global Ph2 trial (IDeate-Lung01 study). Daiichi is also conducting several Ph1/2 studies of I-DXd for other solid tumors.

Figure 34: Clinical trials of I-DXd (B7-H3 ADC)

Registration ID	Indication	Regimen	Sponsor	Trial phase	First posted	Completion date	Participants number
NCT06203210/ IDeate-Lung02	2L SCLC	mono vs chemo	Daiichi Sankyo	Ph3	2024-01-12	2028-01-31	468
NCT05280470/ IDeate-Lung01	ES-SCLC (with 1-3 prior lines of treatment)	mono	Daiichi Sankyo	Ph2	2022-03-15	2025-06-20	180
NCT06330064	Multiple solid tumors	mono	Daiichi Sankyo	Ph2	2024-03-26	2028-07-01	260
NCT06362252/ IDeate-Lung03	1L ES-SCLC	+atezolizumab+/-chemo	Daiichi Sankyo	Ph1/2	2024-04-12	2026-12-30	149
NCT04145622	Solid tumors	mono	Daiichi Sankyo	Ph1/2	2019-10-30	2027-03-01	250

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

In SCLC, I-DXd demonstrated durable responses in its Ph1/2 trial ([link](#)). With a median follow-up of 11.7 months, for 21 heavily pretreated SCLC patients (median of two lines of prior therapy) receiving I-DXd (6.4 to 16.0 mg/kg) in the dose escalation part, the ORR was 52.4% with one CR and 10 PRs. An mDOR of 5.9 months was observed. Median PFS was 5.6 months and mOS was 12.2 months as of data cutoff of Jan 2023. Grade 3 or higher TEAEs occurred in 36.4% of patients. The most common TEAEs were nausea (59.1%), fatigue (50.0%), anemia (27.3%), vomiting (27.3%) and decreased appetite (22.7%). There was one grade 2 event confirmed to be treatment-related ILD or pneumonitis. There was one grade 5 event of COVID-19 pneumonia that was determined not to be treatment related.

HS-20093 has demonstrated promising clinical results especially in pre-treated SCLC

Approximately 65% of all SCLC tumors have a moderate-to-high expression of B7-H3, which is associated with disease progression and lower survival. With limited effective treatment options beyond traditional chemotherapy and immunotherapy, later line SCLC can be difficult to treat.

HS-20093's data from the Ph1 China trial (ARTEMIS-001) in advanced solid tumors was presented at the ASCO in May 2023 ([link](#)). Initial clinical activity of HS-20093 was observed in SCLC, NSCLC, and sarcoma with multiple confirmed responses and a manageable safety profile. In the study, the dose escalation part assessed safety and tolerability of intravenous HS-20093 with doses ranging from 1.0 to 16.0 mg/kg, every 3 weeks. In the dose escalation study, 53 patients with multiple tumor types were enrolled including 29 with NSCLC, 11 with SCLC, 9 with sarcoma and 4 with other solid tumors. At baseline, 25 pts (47.2%) had received ≥ 3 prior lines of therapy with a mean of 3.2 prior lines of therapy. The maximum tolerated dose was determined to be 12.0 mg/kg. No interstitial lung disease (ILD) was reported. As of Mar 2023, ORR was 30% in the 50 response-evaluable patients, regardless of baseline B7-H3 expression level, with a DCR rate of 86.0%. The mPFS was 5.4 months. In the subset of 11 evaluable SCLC patients, the ORR was 63.6%, with a median time to first response of 6 weeks. The DCR was 81.8% with a median PFS of 4.7 months and a 3-month PFS rate of 72.7%. HS-20093 also displayed anti-tumor activity in SCLC patients who have progressed on prior derivative of camptothecin treatment.

At the 2024 ASCO meeting, Hansoh released the updated results of the expansion doses of HS-20093 in patients with SCLC from the Ph1a/b ARTEMIS-001 study ([link](#)). The study consisted of dose escalation (1a) and expansion (1b) part. As of Nov 2023, 56 ES-SCLC patients pre-treated with platinum-based standard therapy were enrolled at the expansion dose of 8.0 mg/kg (n=31) or 10.0 mg/kg (n=25). Median prior lines of therapy was 2.0. All patients received platinum plus etoposide and 73.2% (41/56) received immunotherapy. The most common grade ≥ 3 TRAEs were neutropenia, leukopenia, lymphopenia, thrombocytopenia and anemia. 52 patients were efficacy evaluable (8.0 mg/kg: 31 pts; 10.0 mg/kg: 21 pts). HS-20093 showed encouraging efficacy in relapsed ES-SCLC, with ORR of 58.1%/57.1%, mPFS of 5.6/NA months in the 8mg/10mg dose cohorts.

Figure 35: Ph1a/b results of HS-20093 in relapsed ES-SCLC

	8.0 mg/kg Q3W (n=31)	10.0 mg/kg Q3W (n=21)
ORR, n (%), (95% CI)	18 (58.1%)* (39.1, 75.5)	12 (57.1%) [#] (34.0, 78.2)
DCR, n (%), (95% CI)	25 (80.6%) (62.5, 92.5)	20 (95.2%) (76.2, 99.9)
Median DOR, month, (95% CI)	4.3 (3.3, NA)	NA (3.1, NA)
Median PFS, month, (95% CI)	5.6 (3.4, NA)	NA (4.4, NA)
Median follow-up time, month, (95% CI)	4.8 (3.6, 5.6)	4.9 (4.1, 5.6)

*Fifteen pts were confirmed PRs, 3 pts are awaiting confirmation.

[#]Ten pts were confirmed PRs, 2 pts are awaiting confirmation. ORR: objective response rate, DCR: disease control rate, DOR: duration of response; PFS: progression free survival, CI: confidence interval, PR: partial response.

Source: Company data, CMBIGM

In cross-trial comparison of the early clinical results, for heavily pretreated SCLC patients, HS-20093's 58.1%/57.1% ORR and 5.6/NA months of mPFS were comparable to I-DXd's 52.4% ORR and 5.6 months of mPFS. Additionally, similar to Daiichi's other ADC drugs, I-DXd's adverse effect of ILD could be a concern, while no ILD cases were observed in HS-20093's Ph1a/b study. Note that in the Ph3 ARTEMIS-008 and ARTEMIS-009 studies, HS-20093 adopted the dose of 8mg/kg Q3W.

Figure 36: Comparison of B7-H3 ADCs in SCLC

	HS-20093	I-DXd
Company	Hansoh/ GSK	Daiichi Sankyo/ MSD
mAb	B7-H3 mAb	MABX-9001a (B7-H3 mAb)
Linker	--	thioether (cleavable)
Payload	Topo I inhibitor	Deruxtecan (DXd, a DNA topo I inhibitor)
DAR	4	4
Trial ID	NCT05276609, Ph1	NCT04145622, Ph1/2
Dose	8 or 10mg/kg, Q3W	6.4-16.0mg/kg, Q3W
Patient number	52 (31 vs 21 in 8 or 10mg/kg)	21
Baseline	Median of two lines of prior therapy, 73.2% received prior immunotherapy	Median of two lines of prior therapy, the majority were treated with platinum-based chemotherapy and immunotherapy
ORR	58.1% (8mg) , 57.1% (10mg)	52.4%
mDoR	4.3 months (8mg), NA (10mg)	5.9 months
mPFS	5.6 months (8mg) , NA (10mg)	5.6 months
mOS	--	12.2 months
TEAE (Gr>=3)	--	36.4%
ILD	no ILD	one Gr2 treatment-related ILD or pneumonitis one Gr5 non-treatment-related COVID-19 pneumonia
Latest development	Ph2 in SCLC ongoing, Ph3 trials in SCLC registered (8mg/kg, Q3W)	Ph3 in SCLC ongoing (12mg/kg, Q3W)
Source	Link	Link

Source: PubMed, CMBIGM

Besides SCLC, Hansoh is also evaluating HS-20093 in Ph2 studies for HNSCC, mCRPC, osteosarcoma, etc. The Ph2 results of HS-20093 in heavily-treated R/R osteosarcoma were released at 2024 ASCO meeting ([link](#)). HS-20093 exhibited promising antitumor activities with acceptable toxicity for heavily pretreated R/R osteosarcoma. In the trial, a total of 34 patients with R/R osteosarcoma were enrolled, receiving HS-20093 at the dose of either 8.0 mg/kg (N = 15) or 12.0 mg/kg (N = 19). The incidences of discontinuations, dose withhold and dose reductions were 2.9%, 11.8% and 23.5%, respectively. There was no TEAE leading to death. As of cut-off date (25 Dec 2023), the ORR of 12.0 mg/kg HS-

20093 was 20.0%. The DCR was 81.8% (9/11) and 100% (10/10) in patients with 8 mg/kg and 12.0 mg/kg. These results indicate the broad indication potential of HS-20093.

Forecast HS-20093 to generate RMB4.8bn in risk adjusted peak sales in 2034E

We anticipate that HS-20093 will receive approval in 2027E for the treatment of SCLC, HNSCC, and prostate cancer. With its adoption for second-line (2L) treatment in ES-SCLC, we project that HS-20093 will generate RMB1.6bn in risk-adjusted sales from SCLC alone in 2034E in China, representing 69% of the drug's total risk-adjusted sales of RMB2.3bn for that year within China. Starting from 2028E, we also expect HS-20093 to generate royalties from sales in international markets. When combining the projected revenues from China, international royalties, and milestone payments from GSK, our total revenue forecast for HS-20093 stands at approximately RMB4.8bn in 2034E.

Figure 37: Sales forecast of HS-20093 (B7-H3 ADC)

HS-20093 sales projection	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
HS-20093 sales in SCLC in China (RMB mn)	192	504	1,096	1,897	2,441	2,635	2,681	2,648	2,612
Probability of success in China	60%	60%	60%	60%	60%	60%	60%	60%	60%
HS-20093 sales in HNSCC in China (RMB mn)	133	260	417	594	780	859	889	916	940
Probability of success in China	30%	30%	30%	30%	30%	30%	30%	30%	30%
HS-20093 sales in Prostate Cancer in China (RMB mn)	141	220	331	456	586	676	693	707	719
Probability of success in China	30%	30%	30%	30%	30%	30%	30%	30%	30%
HS-20093 sales in others in China (RMB mn)		50	98	161	208	227	231	231	229
Risk-adjusted China Sales (RMB mn)	198	496	980	1,614	2,083	2,269	2,315	2,307	2,295
YoY		151%	98%	65%	29%	9%	2%	0%	-1%
Risk-adjusted sales from the US (RMB mn)		1,402	3,521	6,954	11,459	14,783	16,104	16,430	16,373
Royalties on sales (RMB mn)		98	282	626	1,146	1,626	1,932	2,136	2,128
% of royalty		7%	8%	9%	10%	11%	12%	13%	13%
Upfront and milestone payment (RMB mn)	325	325	325	325	325	325	325	325	325
Risk-adjusted total revenue for Hanson (RMB mn)	522	919	1,586	2,565	3,553	4,220	4,572	4,767	4,748
SCLC – China (number of people in 000)	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Total SCLC cancer new cases in China	150	155	160	164	168	171	174	178	182
Drug treated 1L SCLC patients	135	139	144	148	151	154	157	160	163
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%	90%
1LSCLC patients adopted B7-H3 ADC	0	0	1	6	11	12	14	14	15
1L B7-H3 ADC adoption rate	0%	0%	1%	4%	7%	8%	9%	9%	9%
Eligible 2L SCLC patients	95	98	100	99	98	99	100	102	104
% 1L patients entering 2L	70%	70%	70%	70%	70%	70%	70%	70%	70%
Drug treated 2L SCLC patients	81	83	85	85	84	84	85	87	88
% 2L treatment rate	85%	85%	85%	85%	85%	85%	85%	85%	85%
2L SCLC patients adopted B7-H3 ADC	2	8	17	25	29	30	31	33	34
2L B7-H3 ADC adoption rate	3%	10%	20%	30%	35%	36%	37%	38%	39%
Patients on HS-20093 for SCLC	2	7	14	23	28	29	31	31	31
Volume share of HS-20093 for SCLC	90%	80%	75%	73%	71%	69%	67%	65%	63%
Monthly cost of HS-20093 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717	17,363
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month	4.0	4.3	4.6	4.9	5.2	5.5	5.5	5.5	5.5
HS-20093 sales from SCLC (hospital level, RMB mn)	218	571	1,242	2,149	2,766	2,986	3,037	3,000	2,960
HS-20093 sales from SCLC (exfactory, RMB mn)	192	504	1,096	1,897	2,441	2,635	2,681	2,648	2,612
HNSCC – China (number of people in 000)	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
HNSCC new cases in China ('000 ppl)	141	144	147	150	153	156	159	162	165
Diagnosed incident stage III/IV HNSCC patients	106	108	110	112	115	117	119	122	124
% of HNSCC diagnosed incidence patient in stage III/ IV	75%	75%	75%	75%	75%	75%	75%	75%	75%
Diagnosed incident early stage HNSCC patients	35	36	37	37	38	39	40	41	41
% of HNSCC diagnosed incidence patient in early stage	25%	25%	25%	25%	25%	25%	25%	25%	25%
Recurrent patient pool	18	18	18	19	19	19	20	20	21
% early stage recurrent rate	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total 1L HNSCC new cases in China	123	126	128	131	134	136	139	142	145
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%	90%
Eligible 2L HNSCC patients	99	101	103	105	107	109	111	113	116
% 1L patients entering 2L	80%	80%	80%	80%	80%	80%	80%	80%	80%
Drug treated 2L HNSCC patients	84	86	87	89	91	93	95	96	98
% 2L treatment rate	85%	85%	85%	85%	85%	85%	85%	85%	85%
2L HNSCC patients adopted B7-H3 ADC	2	4	7	10	13	14	15	16	18
2L B7-H3 ADC adoption rate	2%	5%	8%	11%	14%	15%	16%	17%	18%
Patients on HS-20093 for 2L HNSCC	2	3	5	7	9	10	10	11	11
Volume share of HS-20093 for 2L HNSCC	90%	80%	75%	73%	71%	69%	67%	65%	63%

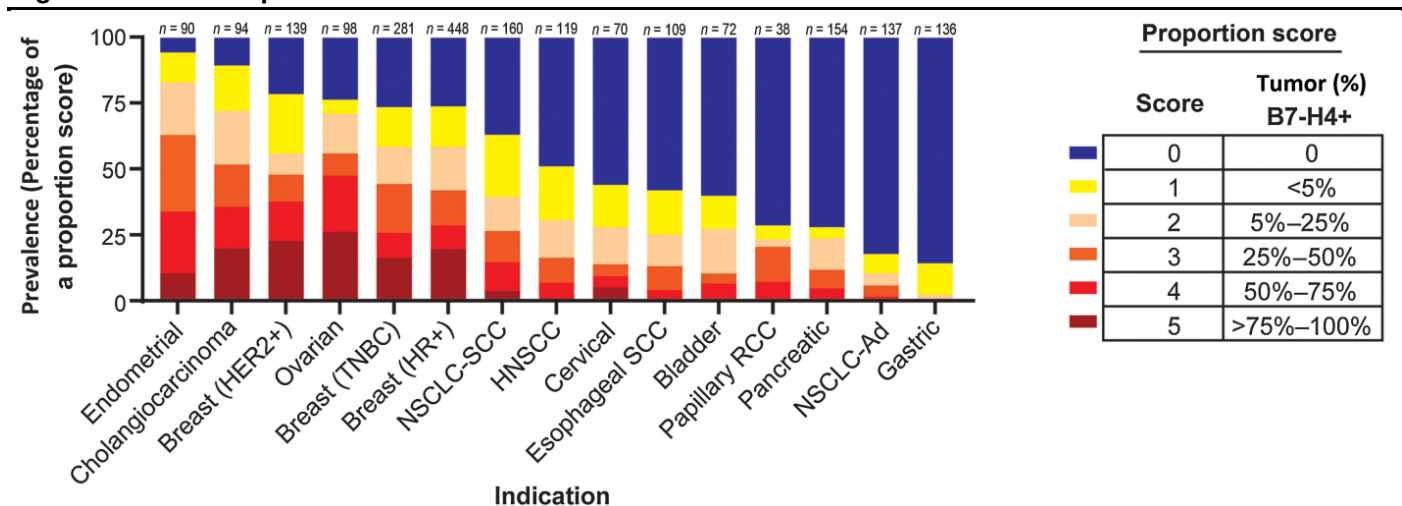
Monthly cost of HS-20093 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717	17,363
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month	4.0	4.3	4.6	4.9	5.2	5.5	5.5	5.5	5.5
HS-20093 sales from HNSCC (hospital level, RMB mn)	151	295	473	673	884	973	1,008	1,038	1,065
HS-20093 sales from HNSCC (exfactory, RMB mn)	133	260	417	594	780	859	889	916	940
mCRPC – China (number of people in 000)	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Incidence of PC in China	141	142	144	145	147	148	150	151	153
mCRPC as % of total PC patients	50%	50%	50%	50%	50%	50%	50%	50%	50%
Incidence of mCRPC in China	71	71	72	73	73	74	75	76	76
Eligible 1L mCRPC patients in China	63	64	65	65	66	67	67	68	69
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%	90%
Eligible 2L mCRPC patients in China	41	41	41	42	42	43	43	44	44
% 1L patients entering 2L	80%	80%	80%	80%	80%	80%	80%	80%	80%
Treatment rate of 2L mCRPC in China	80%	80%	80%	80%	80%	80%	80%	80%	80%
2L mCRPC patients adopted B7-H3 ADC	2	4	6	8	11	13	14	15	16
Penetration of B7-H3 ADC among 2L mCRPC patients	5%	10%	15%	20%	25%	30%	32%	34%	36%
mCRPC patients on HS-20093	2	3	5	6	8	9	9	10	10
HS-20093 market share in 2L mCRPC patients	90%	80%	75%	73%	71%	69%	67%	65%	63%
Montly cost of HS-20093 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717	17,363
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month	3.5	3.8	4.1	4.4	4.7	4.7	4.7	4.7	4.7
HS-20093 sales from mCRPC (hospital level, RMB mn)	160	249	375	516	664	766	786	801	814
HS-20093 sales from mCRPC (exfactory, RMB mn)	141	220	331	456	586	676	693	707	719

Source: CMBIGM

HS-20089 (B7-H4 ADC), early signals demonstrated FIC/BIC potential

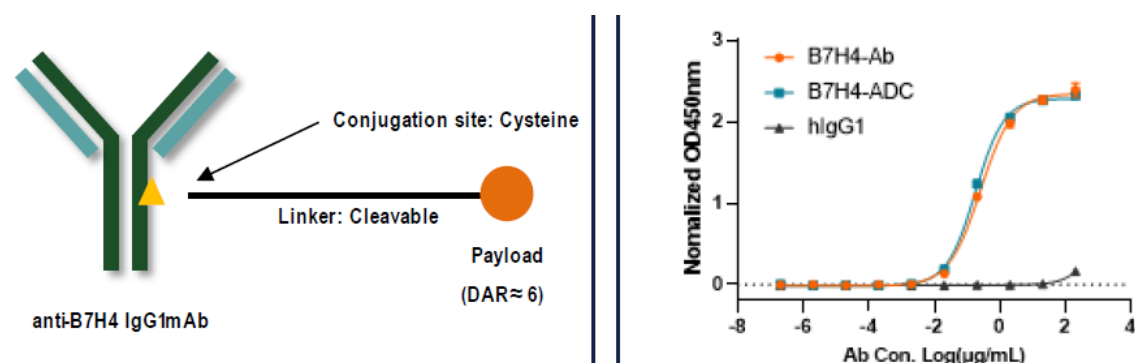
B7-H4, a transmembrane glycoprotein in the B7 superfamily, has limited expression in normal tissues but is highly expressed in various cancers, and could be a promising target for immunotherapy.

Figure 38: B7-H4 expression in human tumors



Source: PubMed, CMBIGM. Note: The prevalence of B7-H4 expression in an indication is shown by the proportion of cells expressing B7-H4 positivity at any intensity.

HS-20089 is an investigational ADC, which is composed of a humanized IgG1 anti-B7-H4 mAb conjugated to the topoisomerase I inhibitor payload via a protease-cleavable linker, with an average DAR of about 6. HS-20089 being developed for the treatment of gynaecologic cancers (ovarian and endometrial cancers) in clinical studies in China, with strong opportunities in other solid tumors.

Figure 39: Structure and binding activity of HS-20089

Source: Company data, CMBIGM

In Oct 2023, Hansoh granted the ex-China rights of HS-20089 to GSK. Under the agreement, Hansoh received an US\$85mn upfront payment and will be eligible to receive up to US\$1.485bn milestone fees and tiered royalties on overseas net sales. GSK's PD-1 mAb dostarlimab/Jemperli has been approved in the US for endometrial cancer, and will serve as a backbone for HS-20089 combination in endometrial cancer. We think GSK will explore HS-20089's combination potential with dostarlimab. GSK has registered a global Ph1 study (NCT06431594) of HS-20089/GSK5733584 in May 2024.

Hansoh is conducting several early clinical studies of HS-20089 in China, including a Ph2 study assessing HS-200089 as monotherapy for treatment of recurrent/ relapsed ovarian cancer and endometrial cancer.

Figure 40: Clinical trials of HS-20089 (B7-H4 ADC) conducted by Hansoh

Trial ID	Regimen	Indication	Stage	Start date	Completion date	Patient number
NCT06014190	mono	Ovarian cancer and endometrial cancer	Ph2	2023-08-28	2027-12-31	460
NCT06336707	+ adebrelimab (PD-L1) +/- chemo; + bevacizumab +/- chemo	Solid tumors	Ph1	2024-03-29	2028-04-08	1048
NCT05263479	mono	Breast cancer, ovarian cancer, and other solid tumors	Ph1	2022-03-02	2026-12-31	177

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

The Ph1 data of HS-20089 in patients with advanced solid tumors was released at the ESMO 2023 ([link1](#), [link2](#)). In the study, escalating dose cohorts (0.7 to 7.2 mg/kg) of HS-20089 was administered intravenously every 3 weeks. As of Jun 2023, 52 patients with advanced solid tumors (48 breast cancers, 3 ovarian cancers, and 1 endometrial cancer) received HS-20089 treatment. There were 3 patients experienced DLTs (1 patient at 5.8mg/kg and 2 patients at 7.2 mg/kg). The max tolerated dose was defined as 5.8mg/kg. No ILD and infusion reaction were reported. The most common Gr≥3 TRAEs were hematological toxicity, and the incidence of ≥Gr3 gastrointestinal toxicity was relatively low. SAEs occurred in 13.5% of the overall patients (n=52). There was no AEs leading to treatment discontinuation.

The enrolled patients were heavily pre-treated, with a mean 4.8 prior lines of systemic treatment. As of Jun 2023, the median follow-up was 5.7 months. Of 33 response-evaluable patients, 8 PRs were observed (ORR 24.2%), including 3 confirmed PRs and 5 PRs awaiting confirmation. The DCR was 63.6%.

HS-20089 demonstrated promising early signal in TBNC. In the subset of 28 TNBC patients of the Ph1 study, 8 PRs were observed (ORR 28.6%). At the potential target therapeutic dose (4.8 and 5.8 mg/kg), 7 PRs of 23 pts were observed (ORR 30.4%) in TNBC.

Figure 41: HS-20089's summary of safety in Ph1 study

Category	0.7 mg/kg (N=3) n(%)	1.4 mg/kg (N=3) n(%)	2.8 mg/kg (N=3) n(%)	4.8 mg/kg (N=23) n(%)	5.8 mg/kg (N=14) n(%)	7.2 mg/kg (N=6) n(%)	Total (N=52) n(%)
Any TEAEs	2(66.7)	3(100.0)	3(100.0)	23(100.0)	14(100.0)	6(100.0)	51(98.1)
Any TRAEs	2(66.7)	3(100.0)	3(100.0)	23(100.0)	14(100.0)	6(100.0)	51(98.1)
SAEs	0	0	0	2(8.7)	4(28.6)	1(16.7)	7(13.5)
Leading to dose reduction	0	0	0	2(8.7)	4(28.6)	2(33.3)	8(15.4)
Leading to treatment discontinuation	0	0	0	0	0	0	0
Leading to death	0	0	0	0	0	0	0

TEAEs: Treatment -emergent adverse events, defines as "an event that emerges during treatment of HS -20089".
 TRAEs: Treatment -related adverse events, which includes "Definitely related", "Possibly related", and "Uncertain".
 SAEs: Serious adverse events. Gr. Grade.

Source: Company data, CMBIGM

Figure 42: HS-20089's efficacy in TNBC in Ph1 study



Source: Company data, CMBIGM

Recall that for later-line TNBC patients, Trop2 ADCs also demonstrated encouraging early efficacy signals. For instance, Kelun-Biotech's SKB264 had an ORR of 42.4% ([link](#)), Gilead's Trodelvy had an ORR of 35% ([link](#)), and Daiichi/AZ's Dato-DXd had an ORR of 32% ([link](#)). We think HS-20089 could become another competitive treatment option for TNBC.

Additionally, felmetatug vedotin, a B7-H4 ADC from Seagen/Pfizer, is currently in Ph1 stage. In a Ph1 study, the drug candidate demonstrated 21.4% cORR (n=42) in TNBC ([link](#)).

B7-H4 has become a potential promising target for immunotherapy, with ADCs, bispecific antibodies, monoclonal antibodies currently under early stage development. Hansoh is leading the development of B7-H4 targeted therapies, with HS-20089 currently in Ph2 study for ovarian cancer and endometrial cancer, and in Ph1 studies for other solid tumors.

Figure 43: Global development of B7-H4 targeted therapies

Drug name	MoA	Research institute	CN phase	US phase
HS-20089	anti-B7-H4 ADC; Top inhibitor	GSK; Hansoh Pharma	Phase II	PhI
AZD8205	anti-B7-H4 ADC; Top I inhibitor; camptothecin	AstraZeneca	Phase I/II	Phase I/II
BG-C9074	anti-B7-H4 ADC	DualityBio; BeiGene	Phase I (Australia)	
XMT-1660	anti-B7-H4 ADC; auristatin derivative (MMAE); microtubule inhibitor	Mersana Therapeutics		Phase I
felmetatug vedotin	anti-B7-H4 ADC; auristatin derivative (MMAE); microtubule inhibitor	Seagen (Pfizer)		Phase I
GEN1047	anti-B7-H4/CD3 bsAb	Genmab		Phase I/II
PF-07260437	anti-B7-H4/CD3 bsAb	Pfizer		Phase I
HBM7008	anti-B7-H4/4-1BB bsAb	Harbour BioMed; Cullinan	IND	Phase I
AMP-110	B7-H4-Fc fusion protein	AstraZeneca		Phase I
NC762	anti-B7-H4 mAb	NextCure		Phase I/II
XKH002	anti-B7-H4 mAb	Kanova Biopharma	Phase I	
alsevalimab	anti-B7-H4 mAb	Amgen		Phase I

Source: PubMed, CMBIGM. Note: As of Aug 2024.

HS-20089 to generate RMB1.7bn in risk adjusted peak sales in 2035E

We anticipate that HS-20089 will be approved in 2028E for the treatment of ovarian cancer, endometrial cancer, and TNBC. By 2035E, we project the drug's risk-adjusted sales in China to reach RMB702mn. Additionally, we expect HS-20093 to start generating royalties from overseas sales from 2029E. Combining the projected revenues from China, international royalties, and milestone payments from GSK, we forecast that HS-20089 will generate a total risk-adjusted revenue of RMB1.7bn in 2035E.

Figure 44: Sales forecast of HS-20089 (B7-H4 ADC)

HS-20089 (B7-H4 ADC) sales projection	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
HS-20089 sales in ovarian cancer in China (RMB mn)	123	362	612	847	971	1,078	1,015	1,000
Probability of success in China	30%	30%	30%	30%	30%	30%	30%	30%
HS-20089 sales in endometrial cancer in China (RMB mn)	87	261	439	606	692	766	719	706
Probability of success in China	30%	30%	30%	30%	30%	30%	30%	30%
HS-20089 sales in TNBC in China (RMB mn)	24	131	261	437	609	801	886	951
Probability of success in China	20%	20%	20%	20%	20%	20%	20%	20%
Risk-adjusted China Sales (RMB mn)	68	213	368	523	621	714	697	702
Risk-adjusted sales from the US (RMB mn)		482	1,512	2,611	3,715	4,406	5,065	4,950
Royalties on sales (RMB mn)		34	121	235	371	485	608	643
% of royalty		7%	8%	9%	10%	11%	12%	13%
Upfront and milestone payment (RMB mn)	316	316	316	316	316	316	316	316
Risk-adjusted total revenue for Hanson (RMB mn)	384	563	805	1,075	1,308	1,514	1,621	1,662
Ovarian cancer – China (number of people in 000)	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Ovarian cancer new cases in China	62	63	64	65	66	67	68	69
% of ovarian cancer diagnosed incidence in stage III/ IV	67%	67%	66%	66%	65%	65%	64%	64%
% of ovarian cancer diagnosed incidence patient in early stage	33%	34%	34%	35%	35%	36%	36%	37%
% early stage recurrent rate	70%	70%	70%	70%	70%	70%	70%	70%
Total 1L ovarian cancer cases in China	56	57	58	58	59	60	61	62
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%
% 1L patients entering 2L	80%	80%	80%	80%	80%	80%	80%	80%
Drug treated 2L patients	34	35	35	36	36	37	37	38
% 2L treatment rate	85%	85%	85%	85%	85%	85%	85%	85%
Ovarian cancer patients adopted B7-H4 ADC	1	4	7	10	12	14	14	15
B7-H4 ADC adoption rate	3%	11%	19%	27%	32%	37%	38%	39%
Patients on HS-20089 for 2L ovarian cancer	1	3	5	7	8	9	8	9
Volume share of HS-20089 for 2L ovarian cancer	90%	85%	80%	75%	70%	65%	60%	58%
Monthly cost of HS-20089 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month	6.0	6.3	6.6	6.9	7.2	7.5	7.5	7.5
HS-20089 sales from ovarian cancer (hospital level, RMB mn)	139	410	694	960	1,100	1,222	1,150	1,133
HS-20089 sales from ovarian cancer (exfactory, RMB mn)	123	362	612	847	971	1,078	1,015	1,000
Endometrial cancer – China (number of people in 000)	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Endometrial cancer new cases in China	99	101	102	103	104	105	106	107
% of endometrial cancer diagnosed incidence patient in stage III/ IV	30%	30%	30%	30%	30%	30%	30%	30%
% of endometrial cancer diagnosed incidence patient in early stage	70%	70%	70%	70%	70%	70%	70%	70%
% early stage recurrent rate	15%	15%	15%	15%	15%	15%	15%	15%
Total 1L endometrial cancer cases in China	40	41	41	42	42	43	43	43
% treatment rate	90%	90%	90%	90%	90%	90%	90%	90%

% 1L patients entering 2L	80%	80%	80%	80%	80%	80%	80%	80%
Drug treated 2L patients	24	25	25	26	26	26	26	27
% 2L treatment rate	85%	85%	85%	85%	85%	85%	85%	85%
Endometrial cancer patients adopted B7-H4 ADC	1	3	5	7	8	10	10	10
B7-H4 ADC adoption rate	3%	11%	19%	27%	32%	37%	38%	39%
Patients on HS-20089 for 2L endometrial cancer	1	2	4	5	6	6	6	6
Volume share of HS-20089 for 2L endometrial cancer	90%	85%	80%	75%	70%	65%	60%	58%
Monthly cost of HS-20089 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month	6.0	6.3	6.6	6.9	7.2	7.5	7.5	7.5
Sales from endometrial cancer (hospital level, RMBmn)	99	295	498	686	784	868	815	800
HS-20089 sales from endometrial cancer (exfactory, RMB mn)	87	261	439	606	692	766	719	706
BC – China (number of people in 000)	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Breast cancer new cases in China	483	493	503	513	523	534	544	555
Early stage BC as % of total breast cancer	72%	72%	72%	72%	72%	72%	72%	72%
locally advanced as % of total BC	20%	20%	20%	20%	20%	20%	20%	20%
mBC patients as % of total BC	8%	8%	8%	8%	8%	8%	8%	8%
5-year accumulated eBC relapsed rate	30%	30%	30%	30%	30%	30%	30%	30%
Total 1L BC new cases in China	240	244	249	254	259	265	270	275
% 1L treatment rate	90%	90%	90%	90%	90%	90%	90%	90%
Total 1L TNBC patients	32	33	34	34	35	36	36	37
% TNBC	15%	15%	15%	15%	15%	15%	15%	15%
Total 2L TNBC new cases in China	26	26	27	27	28	29	29	30
% 1L patients entering 2L	80%	80%	80%	80%	80%	80%	80%	80%
Drug treated 2L TNBC patients	22	22	23	23	24	24	25	25
% 2L treatment rate	85%	85%	85%	85%	85%	85%	85%	85%
2L TNBC patients on HS-20089	0	1	3	4	5	7	7	7
Penetration of HS-20089 in 2L TNBC	1%	6%	11%	17%	22%	27%	28%	29%
Monthly cost of HS-20089 (RMB)	25,000	20,000	19,600	19,208	18,824	18,447	18,078	17,717
% price change YoY		-20%	-2%	-2%	-2%	-2%	-2%	-2%
Avg. treatment month (TNBC)	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.3
HS-20089 sales from TNBC (hospital level, RMB mn)	28	148	296	496	690	908	1,003	1,078
HS-20089 sales from TNBC (exfactory, RMB mn)	24	131	261	437	609	801	886	951

Source: CMBIGM

GLP-1 portfolio, to capture the enormous opportunities of obesity

GLP-1Rs enhance insulin secretion and inhibit glucagon secretion in a glucose concentration-dependent manner. Activation of GLP-1Rs can delay gastric emptying and reduce food intake through appetite suppression, resulting in a blood glucose-lowering effect. In addition, these drugs can also reduce body weight, lower blood pressure, and protect the cardiovascular and renal organs. Hansoh has a rich portfolio of GLP-1 assets, including the commercial-stage Fulaimei (polyethylene glycol loxenate Injection, GLP-1), and the clinical-stage HS-20094 (GLP-1/GIP), HS-10501 (oral GLP-1), and others.

Fulaimei (PEGylated loxenate, GLP-1), commercial long-acting GLP-1 for diabetes

Fulaimei is an innovative weekly-dosed GLP-1R agonist developed by Hansoh. The drug was approved in China in May 2019 for Type 2 diabetes, and was first included in the NRDL since Mar 2021. Fulaimei is China's first domestic innovative long-acting GLP-1 drug, and the global first PEGylated long-acting GLP-1 drug. The drug has been included in the Prevention and Therapy Guidelines for Type 2 Diabetes in China (2020 Edition).

According to cross-trial comparisons of Ph3 studies, Fulaimei achieved -1.02% (0.1mg, maintenance dose) and -1.34% (0.2mg) change of HbA1c at week 24 from baseline in T2DM patients, which was better than that of liraglutide's -0.8% (1.2mg, maintenance dose at week 52) and dulaglutide's -0.8% (1.5mg, maintaining dose at week 26), while was weaker than semaglutide -1.4% (0.5mg, maintenance dose at week 30) and other bi-/tri-target molecules.

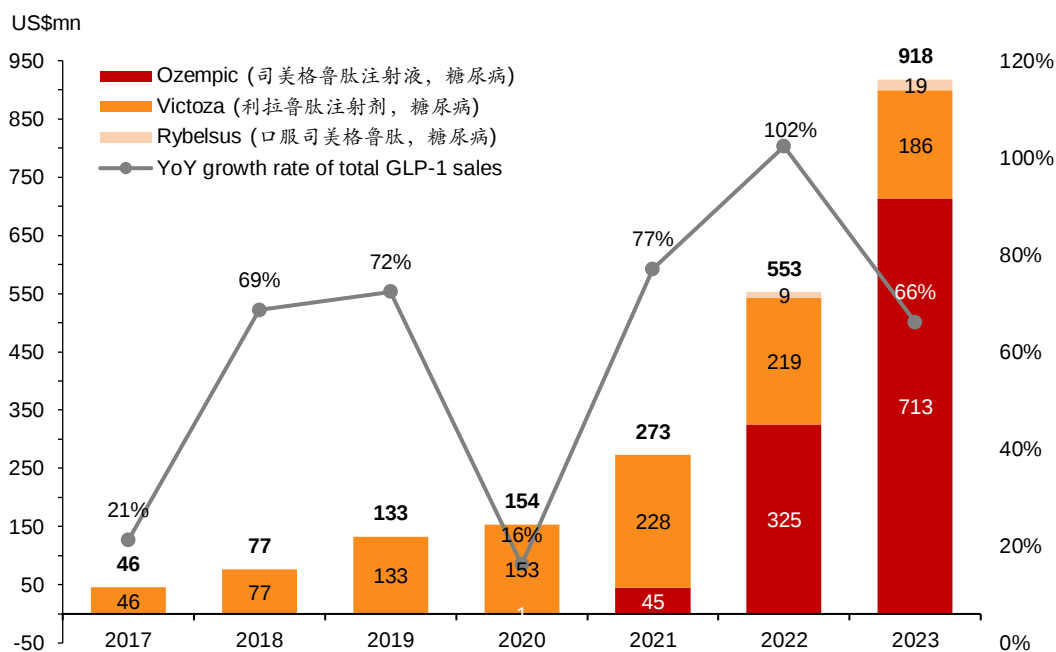
Figure 45: Efficacy of GLP-1R drugs monotherapy in diabetes

	PEG-loxenate	tirzepatide	semaglutide	liraglutide	dulaglutide	mazdutide	retatrutide
Treatment duration (weeks)	24	26	30	52	26	24	24
HbA1c change from baseline (%)	-1.02 (0.1mg) vs -1.34 (0.2mg) vs -0.17 (placebo)	-1.73 (5mg) vs -1.89 (10mg) vs -1.94 (15mg) vs -0.06 (placebo)	-1.4 (0.5mg) vs -1.6 (1mg) vs -0.1 (placebo)	-0.8 (1.2mg) vs -1.1 (1.8mg) vs -0.5 (Glimepiride 8mg)	-0.7 (0.75mg) vs -0.8 (1.5mg) vs -0.6 (metformin 1500-1200mg)	-1.57% (4mg) vs -2.15% (6mg) vs +0.14% (placebo)	-1.88 (8mg) vs -2.02 (12mg) vs -0.01 (placebo) vs -1.41 (1.5mg liraglutide)
Source	Link	Link	Link	Link	Link	Link	Link

Source: PubMed, CMBIGM

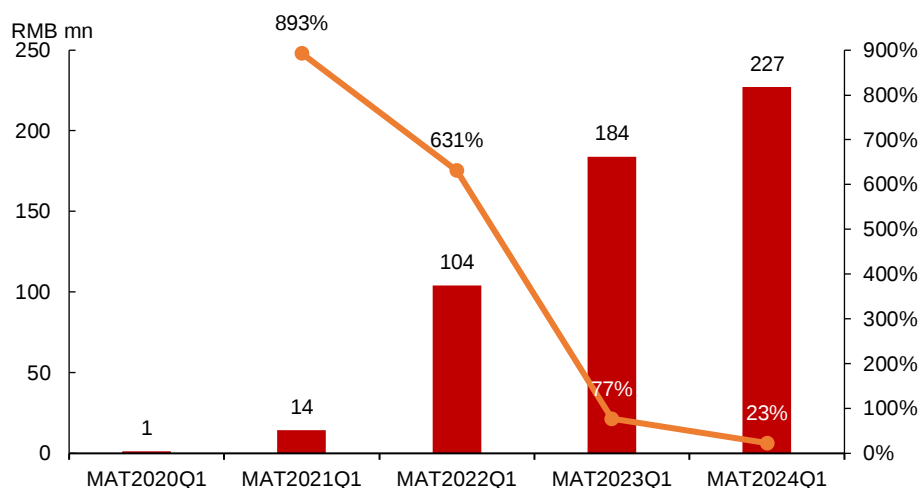
Fulaimei is currently priced at c. RMB440 per month, which is largely inline with semaglutide of c. RMB421 per month. Fulaimei will go through next round of NRDL renewal at end-2024. We think the price of Fulaimei will remain largely stable and expect sales of Fulaimei to grow steadily given the current favorable competition landscape of long-acting GLP-1 drugs in China.

As of Aug 2024, the GLP-1 share of total diabetes prescriptions has increased to 3.3% compared with 3.0% 12 months ago, and Novo Nordisk holds a commanding position in China's GLP-1 market, capturing market share of 79% ([link](#)). In FY23, Novo Nordisk's GLP-1 products generated approximately US\$918mn in sales revenue in China. This suggests that the overall market size of China's GLP-1 sector was around US\$1.2bn in 2023, primarily driven by diabetes treatment, although there may have been some contributions from off-label usage of semaglutide/liraglutide for obesity. According to data from Pharmcube, Fulaimei's sales in sample hospitals has maintained robust growth momentum over the past years, with sales reaching RMB227mn MAT2024Q1 (2Q23-1Q24), marking a YoY increase of 23%.

Figure 46: Sales of Novo Nordisk's GLP-1 drugs in China

Source: Novo Nordisk, CMBIGM.

Figure 47: Fulaimei's sales in sample hospitals



Source: PharmCube, CMBIGM.

The competition within the Chinese GLP-1 market is intense. A multitude of GLP-1 drugs, including innovative drugs and biosimilars, have been approved in China for the treatment of diabetes, and many more are currently in development. Semaglutide and tirzepatide have also received approval in China for the treatment of obesity, which we believe will significantly fuel the growth of the Chinese GLP-1 market. Furthermore, the commercialization of long-acting, dual-target GLP-1 products, such as mazdutide, is imminent in China.

Figure 48: Approved/BLA GLP-1 drugs in China

Drug	MoA	Company	Dose	Indication	Initial approval date in China	Initial NRDL inclusion
Innovative drugs						
exenatide (艾塞那肽)	GLP-1R	Eli Lilly;AZ;BMS	Twice per day	T2DM	2009	2019
liraglutide (利拉鲁肽)	GLP-1R	Novo Nordisk	daily	T2DM	2011	2017
benaglutide (贝那鲁肽)	GLP-1R	Benemae Pharma	3 times per day	T2DM;obesity	2016	2020
lixisenatide (利司那肽)	GLP-1R	AZ;Sanofi	daily	T2DM	2017	2019
Bydureon (艾塞那肽周制剂)	GLP-1R	AZ;BMS;Alkermes	weekly	T2DM	2018	2019
dulaglutide (度拉糖肽)	GLP-1R	Eli Lilly	weekly	T2DM	2019	2020
PEGylated loxenate (聚乙二醇洛塞那肽)	GLP-1R	Hansoh	weekly	T2DM	2019	2020
semaglutide (司美格鲁肽)	GLP-1R	Novo Nordisk	weekly	T2DM;obesity	2021.04 (T2DM, injection); 2024.01 (T2DM, oral) 2024.06 (obesity)	2021 (T2DM)
tirzepatide (替尔泊肽)	GLP-1R; GIPR	Eli Lilly	weekly	T2DM	2024.05 (T2DM); 2024.07 (obesity)	-
mazdutide (玛仕度肽)	GLP-1R; GCGR	Innovent;Eli Lilly	weekly	obesity	NDA (obesity in 2024.02, T2DM in 2024.08)	-
albenatide (艾本那肽)	GLP-1R	ConjuChem; Changshan Biochemical Pharma	weekly	T2DM	NDA	-
PB-119 (维派那肽)	GLP-1R	PegBio	weekly	T2DM	NDA	-
supaglutide (苏帕鲁肽)	GLP-1R	InnoGen	weekly	T2DM	NDA	-
Biosimilars						
liraglutide (利拉鲁肽)	GLP-1R	Huadong Medicine	daily	T2DM;obesity	2023.03 (T2DM); 2023.07 (obesity)	-
liraglutide (利拉鲁肽)	GLP-1R	Kexing Biopharma;Tonghua Dongbao	daily	T2DM	2023	-

liraglutide (利拉鲁肽)	GLP-1R	Chia Tai Tianqing	daily	T2DM	2024	-
liraglutide (利拉鲁肽)	GLP-1R	JYMed Technology	daily	T2DM	biosimilar application	-
liraglutide (利拉鲁肽)	GLP-1R	Hikma Pharma; Hybio Pharmac	daily	T2DM	biosimilar application	-
liraglutide (利拉鲁肽)	GLP-1R	ShengNuo Biotech	daily	T2DM	biosimilar application	-
liraglutide (利拉鲁肽)	GLP-1R	United Laboratories	daily	T2DM	biosimilar application	-
semaglutide (司美格鲁肽)	GLP-1R	Jiuyuan Gene	weekly	T2DM	biosimilar application	-
semaglutide (司美格鲁肽)	GLP-1R	Livzon Pharma	weekly	T2DM	biosimilar application	-
dulaglutide (度拉糖肽)	GLP-1R	Boan Biotech	weekly	T2DM	biosimilar application	-

Source: PharmaCube, CMBIGM. Note: As of Aug 2024.

HS-20094, one of the most advanced dual GLP-1/GIP dual agonists in China

HS-20094 is a new-generation weekly-administrated GLP-1/GIP dual agonist, inhouse developed by Hansoh, which agonizes the downstream pathway by selectively activating both the GLP-1 and GIP receptors to realize biological effects such as reducing glucose and body weight. The drug candidate is currently in Ph2 trials for diabetes and obesity in China. Hansoh plans to initiate a Ph3 study of HS-20094 for obesity in 2H24, followed by a Ph3 study for diabetes in 2025.

Figure 49: Clinical trials of HS-20094

Trial ID	Indication	Stage	Location	Start date	Estimate date of completion	Patient number
NCT06118021	Overweight and obesity	Phase II	China	2023-10-16	2024-10-16	200
NCT06118008	T2DM	Phase II	China	2023-11-07	2024-02-01	96
NCT05116410	Healthy subjects	Phase I	China	2021-11-01	2022-12-31	68

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

The Ph1 dose-escalation data of HS-20094 in healthy subjects were released at the IDF congress in Dec 2023 ([link](#)). The study shows that HS-20094 exhibits good safety, well tolerance, and a good effect in reducing glucose and body weight in healthy adults. The most frequent side effects were mild to moderate decreased appetite and nausea. No increase in dose-dependent gastrointestinal adverse events was observed. A dose-dependent weight loss was observed. The mean reduction of body weight from baseline was 4.74kg on day 29 in the 15mg dose cohort.

The Ph2 (NCT06118008) PoC results of HS-20094 in T2DM was released at ADA meeting in Jun 2024 ([link](#)). Patients with T2DM poorly controlled with diet and exercise alone or with stable metformin (HbA1c ≥ 7.0 to $\leq 10.0\%$) were randomly (4:1:1) assigned within each cohort to receive HS-20094 (5mg, 10mg or 15mg), semaglutide (1.0mg), or placebo subcutaneously once-weekly. The primary outcome was the change in HbA1c from baseline to week 4. Among the 54 subjects, least square mean (LSM) change in HbA1c was -0.63%, -0.75%, -0.84%, and -0.59% in HS-20094 of 5mg, 10mg, 15mg and semaglutide, respectively (all $p < 0.01$ vs placebo). LSM percent change in body weight was -1.27%, -2.51%, -4.41%, and -1.35%, respectively ($p = 0.192$, $p = 0.016$, $p < 0.001$, and $p = 0.179$ vs placebo). The occurrence of AEs was not dose-dependent in HS-20094. The most common AE included decreased appetite, abdominal distension and vomiting. No severe hypoglycemia was reported. Within a 4-week short treatment period, HS-20094 has showed better efficacy potential than semaglutide, especially in the HS-20094 10mg and 15mg dose cohorts.

Tirzepatide (GLP-1/GIP) has been approved for obesity in the US and in China. The competition of GLP-1 drug development is fierce in China. For GLP-1/GIP dual agonists targeting obesity indication, four domestic drug candidates are in Ph2/3 stage, including HRS9531 (Hengrui), HS-20094 (Hansoh), RAY1225 (Raynovent 众生睿创) and BGM0504 (BrightGene 博瑞医药). For GLP-1/GCGR dual agonists, mazdutide developed by Innovent has filed NDA and survodutide developed by BI is under Ph3 study. Additionally, Amgen's GLP-1R agonist and GIPR antagonist AMG133

is also in Ph2 trial for obesity. We think the key success factor of GLP-1 obesity drug in China will be efficacy, timing of approval and manufacturing capacity. We think Hansoh, as one of the early movers in innovative GLP-1 development, will seize a meaningful share in China's obesity market.

Additionally, Hansoh is also developing HS-10501 (oral GLP-1 drug), which is currently in Ph1 stage intended to be used for the treatment of T2DM and obesity.

Figure 50: GLP-1 innovative drugs / drug candidates in China for obesity

Drug name	Target	Company	China stage	US stage
benaglutide	GLP-1R	Benemae Pharma	Approved	
semaglutide	GLP-1R	Novo Nordisk	Approved	Approved
tirzepatide	GLP-1R;GIPR	Eli Lilly	Approved	Approved
mazdutide	GLP-1R;GCGR;OXM	Innovent;Eli Lilly	NDA filed	Ph2
liraglutide	GLP-1R	Novo Nordisk	Ph3 *	Approved
Rybelsus (oral semaglutide)	GLP-1R	Novo Nordisk	Ph3	Ph3
GX-G6	GLP-1R	CSPC; IMAB;Tasly;Genexine	Ph3	
cagrilintide+semaglutide	amylin;GLP-1R	Novo Nordisk	Ph3	Ph3
ecnoglutide	GLP-1R	Sciwind Biosciences; Kawin Technology	Ph3	
orforglipron	GLP-1R	Eli Lilly;Chugai	Ph3	Ph3
retatrutide	GLP-1R;GCGR;GIPR	Eli Lilly	Ph3	Ph3
survodutide	GLP-1R;GCGR	BI;Zealand Pharma	Ph3	Ph3
HRS9531	GLP-1R;GIPR	Hengrui	Ph3	
supaglutide	GLP-1R	InnoGen	Ph2	
HS-20094	GLP-1R;GIPR	Hansoh	Ph2	
RAY1225	GLP-1R;GIPR	Raynovent	Ph2	
BGM0504	GLP-1R;GIPR	BrightGene	Ph2	
maridebart cafraglutide /AMG 133	GLP-1R agonist; GIPR antagonist	Amgen	Ph2	Ph2
GZR18	GLP-1R	Gan Lee Pharmaceuticals	Ph2	
HDM1002	GLP-1R	Huadong Medicines	Ph2	
HRS-7535	GLP-1R	Hengrui	Ph2	
VCT220	GLP-1R	Vincentage	Ph2	
danuglipron	GLP-1R	Pfizer	Ph2	Ph2
noiiglutide	GLP-1R	Hansoh;Hengrui	Ph2	
ZT002	GLP-1R	QL Biopharm	Ph2	
ECC5004	GLP-1R	AstraZeneca;Eccogene	Ph2	Ph2
HEC88473	FGF21;GLP-1	HEC Pharma (Guangdong HEC)	Ph2	
MWN101	GLP-1R;GIPR;GCGR	Minwei Biotech	Ph2	
glutazumab	GLP-1R	Gmax Biopharm	Ph1/2	
MDR-001	GLP-1R	MindRank AI	Ph1/2	
PB-718	GLP-1R;GCGR	PegBio	Ph1/2	
PB-119	GLP-1R	PegBio	Ph1/2	
JY09	GLP-1R	Eastern Biotech;Jingyi Taixiang	Ph1	
DR10624	FGF21;GLP-1R;GCGR	Doer Biologics	Ph1	
GMA106	GLP-1R;GIPR	Gmax Biopharm;Sino Biopharmaceutical	Ph1	
APH01727	GLP-1R	ApicHope	Ph1	
HDM1005	GLP-1R;GIPR	Huadong Medicine	Ph1	IND
HSK34890	GLP-1R	Haisco Pharmaceutical	Ph1	
HZ012	GLP-1R;GIPR	Heze Pharma;Doer Biologics	Ph1	
KN069	GLP-1R;GIPR	Alphamab Oncology;Amoytop Biotech	Ph1	
SAL0112	GLP-1R	Salubris Pharmaceuticals	Ph1	
THDBH120	GLP-1R;GIPR	WuXi AppTec;Tonghua Dongbao	Ph1	
UBT251	GLP-1R;GCGR;GIPR	United Laboratories	Ph1	IND
ZX2010	GLP-1R;GIPR	Kanion Pharmaceutical	Ph1	
ZX2021	GLP-1R;GCGR;GIPR	Kanion Pharmaceutical	Ph1	

Source: PubMed, CMBIGM. Note: As of Aug 2024. Liraglutide biosimilar from Huadong Medicine was approved for obesity, while the original drug was not approved for the obesity indication in China.

HS-20094 to generate RMB2.4bn risk-adjusted peak sales in 2034E

We expect HS-20094 to be approved in 2027E for the treatment of diabetes and obesity. We forecast the risk-adjusted peak sales of HS-20094 to reach RMB2.4bn in 2034E, with RMB1.5bn (or 61%) coming from obesity. In terms of non-risk adjusted revenue, we forecast HS-200094 to realize RMB2.98bn non-risk adjusted revenue from obesity in 2034E,

with assumptions including 1) 268mn obesity population in China in 2034E, 2) 12.8% of obesity patients receiving treatment by 2034E, 3) 44.0% penetration of GLP-1 class drugs in treated obesity patients, 4) a price of RMB808 per month by 2034E, 5) HS-20094 taking 3.6% volume share in GLP-1 drugs in 2034E, and 6) 64% compliance rate of obesity patients taking GLP-1 drugs in 2034E.

Figure 51: Sales forecast of HS-20094 (GLP-1/GIP dual agonists)

HS-20094 (GLP-1/GIP) sales projection	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
HS-20094 sales in diabetes in China (RMB mn)	137	476	902	1,419	1,703	1,844	1,888	1,877	1,855
Probability of success in China	50%	50%	50%	50%	50%	50%	50%	50%	50%
HS-20094 sales in obesity in China (RMB mn)	166	629	1,303	2,231	2,727	2,912	2,951	2,977	2,908
Probability of success in China	50%	50%	50%	50%	50%	50%	50%	50%	50%
Risk-adjusted China Sales (RMB mn)	152	553	1,102	1,825	2,215	2,378	2,419	2,427	2,382

Diabetes in China (number of people in 000)	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Population of T2DM in China	148,611	149,919	151,239	152,570	153,912	155,267	156,633	158,012	159,402
YoY change of T2DM population in China	1%	1%	1%	1%	1%	1%	1%	1%	1%
Treatment rate of T2DM in China	37%	38%	38%	39%	39%	40%	40%	41%	41%
Treated T2DM population	54,986	56,220	57,471	58,739	60,026	61,330	62,653	63,995	65,355
Penetration of GLP-1 drugs in T2DM patients in China	6%	7%	8%	8%	9%	10%	10%	11%	11%
T2DM population receiving GLP-1 class drugs	3,244	3,767	4,310	4,875	5,342	5,826	6,328	6,847	7,385
Patients on HS-20094 for diabetes	16	57	108	171	214	233	240	247	251
Volume share of HS-20094 for diabetes	0.5%	1.5%	2.5%	3.5%	4.0%	4.0%	3.8%	3.6%	3.4%
Monthly cost of HS-20094 for T2DM	1,000	970	941	913	885	859	833	808	784
Price change YoY		-3%	-3%	-3%	-3%	-3%	-3%	-3%	-3%
Compliance rate	80%	82%	84%	86%	85%	87%	89%	89%	89%
HS-20094 sales from T2DM (hospital level, RMB mn)	156	539	1,022	1,607	1,930	2,089	2,139	2,127	2,102
Distributor markup	10%	10%	10%	10%	10%	10%	10%	10%	10%
VAT	3%	3%	3%	3%	3%	3%	3%	3%	3%
HS-20094 sales from T2DM (exfactory, RMB mn)	137	476	902	1,419	1,703	1,844	1,888	1,877	1,855

Obesity in China (number of people in 000)	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Population of obesity in China	210,689	218,064	225,696	233,595	241,771	250,233	258,991	268,056	277,438
YoY change of obesity population in China	4%	4%	4%	4%	4%	4%	4%	4%	4%
Treatment rate of obesity in China	9.0%	10.0%	11.0%	12.0%	12.2%	12.4%	12.6%	12.8%	13.0%
Treated obesity population	18,962	21,806	24,827	28,031	29,496	31,029	32,633	34,311	36,067
Penetration of GLP-1 drugs in obesity patients in China	33.0%	36.0%	39.0%	42.0%	42.5%	43.0%	43.5%	44.0%	44.5%
Obesity population receiving GLP-1 class drugs	6,257	7,850	9,682	11,773	12,536	13,342	14,195	15,097	16,050
Patients on HS-20094 for obesity	31	118	242	412	501	534	539	543	546
Volume share of HS-20094 for obesity	0.5%	1.5%	2.5%	3.5%	4.0%	4.0%	3.8%	3.6%	3.4%
Monthly cost of HS-20094 for obesity	1,000	970	941	913	885	859	833	808	784
Price change YoY		-3%	-3%	-3%	-3%	-3%	-3%	-3%	-3%
Compliance rate	50%	52%	54%	56%	58%	60%	62%	64%	64%
HS-20094 sales from obesity (hospital level, RMB mn)	188	713	1,476	2,527	3,090	3,300	3,343	3,373	3,295
Distributor markup	10%	10%	10%	10%	10%	10%	10%	10%	10%
VAT	3%	3%	3%	3%	3%	3%	3%	3%	3%
HS-20094 sales from obesity (exfactory, RMB mn)	166	629	1,303	2,231	2,727	2,912	2,951	2,977	2,908

Source: CMBIGM

HS-10374 (TYK2 inhibitor), an oral therapy for auto-immune diseases

HS-10374, a highly selective TYK2 inhibitor, is currently in Ph2 studies for auto-immune diseases such as plaque psoriasis (NCT06077331) and psoriatic arthritis (NCT06176508). HS-10374 is expected to be a backbone of Hansoh's auto-immune disease business. In Apr 2024, Hansoh in-licensed the Great China rights of QX004N (IL-23p19) from Qyuns Therapeutics with RMB75mn upfront payment and RMB1.032bn milestones payment. QX004N is currently in Ph2 trial (CTR20232772) for plaque psoriasis. We expect QX004N to deliver synergies with HS-10374 in the auto-immune disease market.

For moderate-to-severe plaque psoriasis, biologic and small molecule targeted therapies are the complementary guideline-recommended therapies. The traditional biologic therapy includes TNF- α targeted mAbs, such as etanercept, infliximab, adalimumab, and certolizumab pegol. However, these therapies do not produce effective clinical responses in all patients and may be associated with serious infection. The next generation systematic therapies that are providing

much more effective treatment options mainly include interleukin (IL) targeted biologic therapies, targeting IL-12/IL-23, IL-17, IL-23p19 and IL-36, as well as a couple of small molecule drugs, targeting PDE4, JAK1/2/3 and TYK2.

In the biologics, IL-23p19 antibodies represent a promising therapy for the treatment of psoriasis with better skin clearance (PASI90 >80%). For instance, guselkumab (IL-23p19) demonstrated superiority over secukinumab (IL-17) in a head-to-head study for psoriasis, with PASI90 at week 48 of 84% vs 70% ($p < 0.0001$, [link](#)). Additionally, secukinumab (IL-17) beat ustekinumab (IL-12/IL-23) in a head-to-head study with PASI90 at week 52 of 73% vs 60% ($p < 0.0001$) for psoriasis ([link](#)).

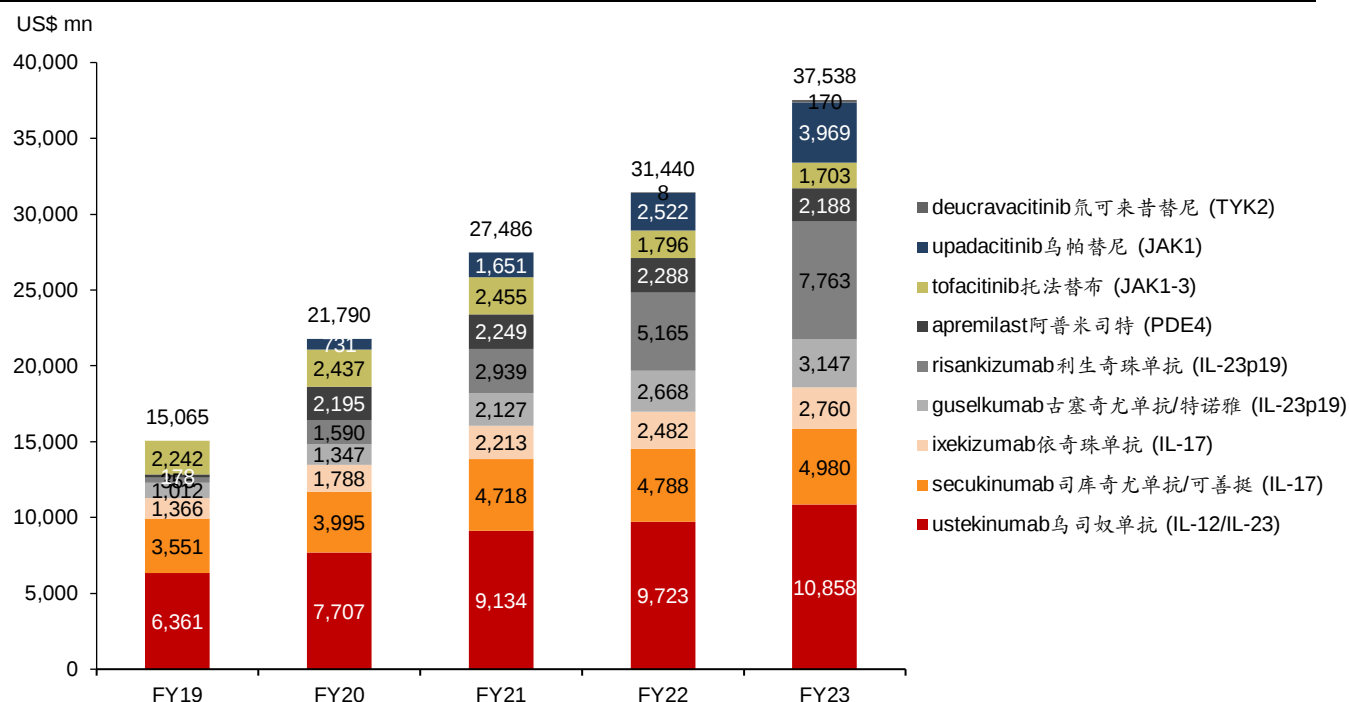
It is worth noting that secukinumab (IL-17 mAb) currently holds a significant portion of the psoriasis market in China. This is partly due to its earlier inclusion in the NRDL since 2021, in our view. According to sales data from PharmCube, the sales of secukinumab in Chinese sample hospitals was RMB1.89bn (+21% YoY) in MAT2024Q1 (2Q23-1Q24), while the sales of guselkumab (IL-23p19) was RMB64mn, and the sales of ustekinumab was RMB394mn during the same period.

Figure 52: Next generation therapies for psoriasis and other autoimmune diseases

Target	Drug name	Chinese name	China approved indications	Initial China approval	US approved indications	Initial US approval time	Initial NRDL coverage date	NRDL valid period	Annual cost in China (RMB)
Biologics									
IL-12/IL-23	ustekinumab	乌司奴单抗	PP, CD	2017	PP, PsA, CD, UC	2009	2022.01	2024.01.01-2025.12.31	20,079
	secukinumab	司库奇尤单抗 / 可善挺	PP, AS	2019	PP, PsA, AS, etc	2015	2021.03	2023.03.01-2024.12.31	27,840
IL-17	ixekizumab	依奇珠单抗	PP, AS	2019	PP, PsA, AS, etc	2016	2022.01	2024.01.01-2025.12.31	20,706
	brodalumab	布罗利尤单抗	PP	2020	PP	2017	-	-	-
	bimekizumab	比吉利珠单抗	-	-	PP	2023	-	-	-
IL-23p19	guselkumab	古塞奇尤单抗 / 特诺雅	PP	2019	PP, PsA	2017	2023.03	2023.03.01-2024.12.31	31,997
	tildrakizumab	替拉珠单抗	PP	2023	PP	2018	2024.01	2024.01.01-2025.12.31	-
	risankizumab	利生奇珠单抗	-	2023.07 BLA	PP, PsA, DC, UC	2019	-	-	-
	mirikizumab	OmvoH	-	-	UC	2023	-	-	-
Small molecule targeted drugs									
PDE4	apremilast	阿普米司特	PP	2021	PP, PsA, etc	2014	2023.03	2023.03.01-2024.12.31	11,204
JAK1-3	tofacitinib	托法替布	PsA, RA, AS	2017	PsA, AS, UC, RA, etc	2012	2023.03	2023.03.01-2024.12.31	11,952
	upadacitinib	乌帕替尼	PsA, RA, AD	2022	PsA, AS, UC, RA, etc	2019	2023.03	2023.03.01-2024.12.31	25,032
TYK2	deucravacitinib	氟可来昔替尼	-	-	PP	2022	-	-	-

Source: PharmCube, CMBIGM. Note: As of Aug 2024.

Globally, the sales of major autoimmune disease drugs, including ustekinumab (IL-12/IL-23), secukinumab (IL-17), ixekizumab (IL-17), guselkumab (IL-23p19), and risankizumab (IL-23p19), are continuing to grow. The TYK2 inhibitor deucravacitinib, at the early stage of commercialization, has recorded strong sales momentum.

Figure 53: Global sales of major autoimmune disease drugs with indication in psoriasis

Source: PharmCube, CMBIGM. Note: Data include global sales of the drugs across all approved indications.

The Janus tyrosine kinases (JAKs) family encompasses four mammalian members: JAK1, JAK2, JAK3, and TYK2. Globally, BMS's Sotyktu (deucravacitinib, 氬可來昔替尼), a highly selective and first-in-class TYK2 inhibitor, has received approval from both the US FDA and China's NMPA for the treatment of adult patients with moderate-to-severe plaque psoriasis. This approval was founded upon the results from the POETIK PSO-1 and POETIK PSO-2 Ph3 studies, which showcased the superior efficacy of once-daily deucravacitinib in improving skin clearance compared to placebo and twice-daily apremilast, a PDE4 inhibitor. In the early stages of its market introduction, deucravacitinib generated global sales of US\$170mn in 2023, and sales of US\$44mn in 1Q24. Additionally, Nimbus Therapeutics' zasocitinib is another highly selective TYK2 inhibitor currently under Ph3 studies. In Feb 2023, Takeda acquired 100% ownership of Nimbus Therapeutics' TYK2 program subsidiary with an upfront payment of US\$4bn, securing global rights to zasocitinib. Several other highly selective TYK2 inhibitors, including Hansoh's HS-10374, are currently in Ph2 studies.

Figure 54: Development landscape of TYK2 inhibitors

Drug name	MoA	Company	China phase	US phase	Note
Highly selective TYK2 (allosteric) inhibitor					
deucravacitinib	TYK2 allosteric inhibitor	Bristol-Myers Squibb	Approved (2023.10, psoriasis)	Approved (2022.09, psoriasis)	SS, SLE, PsA in Ph3; Alopecia Areata, Ulcerative Colitis, Lupus Nephritis, Crohn's Disease in Ph2
zasocitinib	TYK2 allosteric inhibitor	Takeda; Schrödinger; Nimbus	Phase III	Phase III	Psoriasis in Ph3; Ulcerative colitis, Crohn's disease, PsA in Ph2
ESK-001	TYK2 allosteric inhibitor	Haisco; Alumis	Phase II	Phase II	SLE, panuveitis in Ph2
HS-10374	TYK2 allosteric inhibitor	Hansoh	Phase II		Psoriasis, PsA in Ph2
D-2570	TYK2 inhibitor	InventisBio	Phase II		Psoriasis in Ph2
ICP-332	TYK2 inhibitor	InnoCare Pharma	Phase II	Phase I	AD indication in Ph2
ICP-488	TYK2 allosteric inhibitor	InnoCare Pharma	Phase II		Psoriasis in Ph2
ropsacitinib	TYK2 inhibitor	Pfizer; Priovant	IND	Phase II	
GLPG3667	TYK2 inhibitor	Gilead; Galapagos		Phase II	

VTX-958	TYK2 allosteric inhibitor	Ventyx	Phase II
lomeducitinib	TYK2 inhibitor	Bristol-Myers Squibb	Phase II
ARTS-011	TYK2 allosteric inhibitor	Allorion	Phase I
BGB-23339	TYK2 allosteric inhibitor	BeiGene	Phase I
BMS-986465	TYK2 inhibitor	Bristol-Myers Squibb	Phase I
CS32582	TYK2 allosteric inhibitor	Chipscreen	Phase I
FZ007	TYK2 inhibitor	Fermion	Phase I
UA021	TYK2 inhibitor	Usynova	Phase I
WD-890	TYK2 inhibitor	Wenda Pharma	Phase I

Source: Pharmcube, CMBIGM. Note: As of Aug 2024

Sotyktu (Deucravacitinib), already approved for plaque psoriasis, is currently advancing through Ph3 trials for Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome, and Psoriatic Arthritis (PsA). This positions the drug at the forefront of development in the global TYK inhibitor field.

Figure 55: Ph3 Clinical trials of deucravacitinib

Trial ID	Indication	Regimen	Region	First post date	(Estimate) completion date
NCT05946941	Sjögren's Syndrome (SjS)	vs placebo	Global (ex-China mainland)	2023-07-14	2028-11-16
NCT05620407	SLE	vs placebo	Global (ex-China mainland)	2022-11-17	2027-12-17
NCT05617677	SLE	vs placebo	Global (including China)	2022-11-15	2027-12-17
NCT04908189	Psoriatic Arthritis (PsA)	vs placebo vs apremilast (PDE4 inhibitor)	Global (including China)	2021-06-01	2026-11-12
NCT04908202	Psoriatic Arthritis (PsA)	vs placebo	Global (ex-China mainland)	2021-06-01	2027-05-12
NCT04772079	Pediatric Subjects With Moderate to Severe Plaque Psoriasis	vs placebo	Global (ex-China)	2021-02-26	2033-09-08
NCT04167462	Moderate-to-Severe Plaque Psoriasis	vs placebo	China, Korea	2019-11-18	2022-01-07
NCT04036435	Extension Study in Moderate-to-Severe Plaque Psoriasis	vs placebo	Global (including China mainland)	2019-07-29	2026-07-26
NCT03924427	Moderate-to-Severe Psoriasis	vs placebo	Japan	2019-04-23	2021-03-24
NCT03624127	Moderate-to-Severe Plaque Psoriasis	vs placebo vs apremilast (PDE4 inhibitor)	Global (including China mainland)	2018-08-09	2020-09-02
NCT03611751	Moderate-to-Severe Plaque Psoriasis	vs placebo vs apremilast (PDE4 inhibitor)	Global (ex-China)	2018-08-02	2020-11-30

Source: PubMed, CMBIGM. Note: As of Aug 2024.

TYK2 inhibitors have shown promising potential for the treatment of psoriasis, offering patients a convenient oral alternative. In the POETKY PSO-1 trial for psoriasis patients, deucravacitinib achieved a PASI90 score of 44.0% at week 52 ([link](#)), which, while lower than the 84% achieved by guselkumab (IL-23p19), still represents a significant clinical benefit.

Moreover, J&J's Ph3 asset JNJ-2113, the first and only oral peptide designed to block the IL-23 receptor, also demonstrated strong skin clearance in psoriasis patients, with a 64% PASI90 score at week 52 in the Ph2b FRONTIER2 trial ([link](#)). This could potentially provide another convenient oral therapy option for psoriasis upon its approval.

Psoriasis is a chronic, relapsing condition necessitating continuous treatment. The frequent subcutaneous injections of biologic therapies on a bi-weekly or monthly basis pose a significant burden for patients. In contrast, small molecule oral drugs like TYK2 inhibitors offer a more convenient solution. Overall, we anticipate TYK2 inhibitors to emerge as a

validated oral treatment option, gaining reasonable market share in the autoimmune disease space by addressing the need for more convenient therapeutic options for chronic conditions like psoriasis.

HS-10353, a GABA receptor positive allosteric modulator for depression

The GABA system is the major inhibitory signaling pathway of the brain and central nervous system and contributes to regulating brain function. HS-10353 is a new generation of GABAA receptor positive allosteric modulator developed by Hansoh, which can correct the dysfunction of GABAA receptor function and restore the balance between GABA receptor and NMDA receptor. Oral administration of HS-10353 at night for 14 days is expected to reduce clinical symptoms in patients with depression. HS-10353 is currently in Ph2 development for the treatment of major depression disorder (MDD) and postpartum depression (PDD).

Figure 56: Ph2 trials of HS-10353

Trial ID	Indication	Stage	Start date	Estimate date of completion	Patient number
NCT05938179	Major depression disorder (MDD)	Phase II	2023-07-10	2025-04-30	144
NCT05937867	Postpartum depression (PDD)	Phase II	2023-07-10	2025-10-31	96

Source: PharmaCube, CMBIGM

Depression drugs have large market potential worldwide. It is estimated that more than 21 million adults in the US experienced at least one major depressive episode in 2020, with nearly 14 million people diagnosed with major depressive disorder, and an estimated 500K cases of PPD annually. COVID-19 pandemic further triggers 25% increase in prevalence of anxiety and depression worldwide. In China, according to “2022 blue book on national depression”, there are 95 million people with depression in China, while less than 10% of the patients receive treatment.

HS-10353 has the similar MoA with zuranolone. Zuranolone, developed by Sage and Biogen, was approved in the US in Aug 2023 for the treatment of postpartum depression (PDD), which became the first oral medication for PPD patients. The BLA of zuranolone for MDD was rejected by the US FDA with the CRL requiring additional studies to further verify the drug's effectiveness ([link](#)). Zuranolone is a rapid-acting, once-daily, oral neuroactive steroid that can take effect in 14 days, as compared to the most current other approved therapies for depression that may take weeks or months to work. In people with depression, zuranolone is thought to work by rapidly rebalancing dysregulated neuronal networks to help reset brain function. Zuranolone targets brain networks responsible for functions such as mood, arousal, behavior, and cognition. However, zuranolone has a boxed warning of causing driving impairment due to central nervous system depressant effects. Patients taking zuranolone are recommended not to drive during the 14-day treatment course.

HS-10241 (MET TKI) has combination potential with Ameile

MET gene amplification is one of the most frequent acquired resistance mechanisms for EGFR-mutant NSCLC patients following the treatment with prior EGFR-TKI monotherapy. HS-10241, an oral and highly selective small molecule MET-TKI, may overcome common acquired MET-based resistance mechanisms following EGFR-TKI treatment. We envision the potential of HS-10241 being combined with Ameile (aumolertinib) for the treatment of EGFR-TKI-resistant NSCLC patients. A Ph3 registrational trial of HS-10241 + aumolertinib in post-EGFR-TKI NSCLC patients with MET amplification is ongoing.

HS-10241 in combination with aumolertinib was well tolerated, and showed encouraging antitumor activity in treatment of advanced NSCLC with EGFR mutation and MET amplification following prior EGFR-TKI. The Ph1b data of HS-10241 + aumolertinib was presented at the ASCO 2023 ([link](#)). In 22 patients with EGFR mutation regardless of the MET gene status, the ORR was 54.5%. In the 13 patients who had confirmed EGFR mutation and MET-amplification, the ORR was

61.5%. 9 of these 13 patients received both 1st/2nd and 3rd-generation EGFR-TKIs, and there were 6 PRs (ORR 66.7%).

In cross-trial comparison, the efficacy data of HS-10241 + aumolertinib was better than that of savolitinib + osimertinib, which demonstrated 49% ORR in patients with high levels of MET overexpression and/or amplification in the SAVANNAH Ph2 study ([link](#)). A Ph3 registrational trial (NCT06110663) of HS-10241 + aumolertinib in post-EGFR-TKI NSCLC patients with MET amplification is currently ongoing.

HS-10365 (RET-TKI) to further expand the product portfolio in NSCLC

HS-10365 is a highly potent and selective RET TKI, which demonstrated promising anti-tumor activity in patients with RET gene fusion-positive NSCLC, either with or without previous treatments. A Ph2 trial (NCT06147570) is ongoing, evaluating HS-10365 as a first-line treatment for patients with RET fusion-positive NSCLC.

Two selective RET inhibitors, pralsetinib from Blueprint and selpercatinib from Eli Lilly / Innovent, have been approved in China and in the US for RET+ NSCLC and MTC. However, there could be acquired RET drug-resistant mutations and safety issues such as hypertension and hematological toxicity with the first-generation RET inhibitors, underscoring the need for novel selective RET inhibitors with improved safety and efficacy against drug resistant mutations.

The Ph1 data of HS-10365 as mono therapy was presented at AACR 2023, which showed a manageable safety profile and favorable pharmacokinetic properties ([link](#)). In the Ph1 study, as of Dec 2022, 31 RET fusion+ NSCLC patient received HS-10365, including 25 patients previously received platinum-based chemotherapy and 6 treatment-naïve patients. No patients discontinued treatment owing to AEs. 160mg BID was the potentially recommended Ph2 dose. Efficacy data was available for 30 RET fusion+ NSCLC patients with 24 pretreated patients and 6 treatment naïve patients. The ORR was 70.0% (21/30), with 66.7% (16/24) in pretreated patients and 83.3% (5/6) in treatment naïve patients.

In cross-trial comparison, selpercatinib delivered 84% ORR in treatment-naïve patients and 61% ORR in pretreated patients. Similarly, pralsetinib showed an ORR of 78% and 63% in treatment-naïve patients and previously treated patients, respectively.

Figure 57: Cross-trial comparison of RET inhibitors in NSCLC

Drug	HS-10365	Selpercatinib	Pralsetinib
Company	Hansoh	Eli Lilly / Innovent	Blueprint / CStone
Trial ID	NCT05207787	LIBRETTO-001, Ph1/2	ARROW, Ph1/2
Patient no.	30	316	237
Baseline	6 treatment naïve pts; 24 pretreated pts	For later line: 43% pts received ≥3 prior treatment	For later line: median prior 2 treatments, 42% with PD(L)1
ORR	83.3% (5/6) in treatment naïve pts; 66.7% (16/24) in pretreated pts	84% for 1L pts (6% CR, n=69); 61% for pre-treated pts (7% CR, n=247)	78% for 1L pts (7% CR, n=107); 63% for pre-treated pts (6% CR, n=130)
mPFS	-	22.0 mos for 1L pts; 24.9 mos for pre-treated pts	-
TRAEs led to dose reduction	-	30.0%	-
TRAEs led to discontinuation	No pts discontinued due to AEs	2.0%	-
Hypertension	-	14% Gr 3 or 4	18% Gr 3 or 4
QT interval prolongation	-	-	-
Platelets decrease	-	-	5% Gr 3 or 4
Lymphocytes decrease	-	-	32% Gr 3 or 4
Others	The common (>25%) TRAEs were AST increase, bilirubin increase, ALT increase, WBC decrease, PLT decrease, neutrophil decrease, etc.	Warnings for hepatotoxicity, ILD, hypertension, QT interval prolongation, hemorrhagic events, etc in the label	Warnings for ILD, hypertension, hepatotoxicity, hemorrhagic events, etc in the label
Source	Link	Link1 , Link2	Link

Source: Company data, FDA labels, Pubmed, CMBIGM

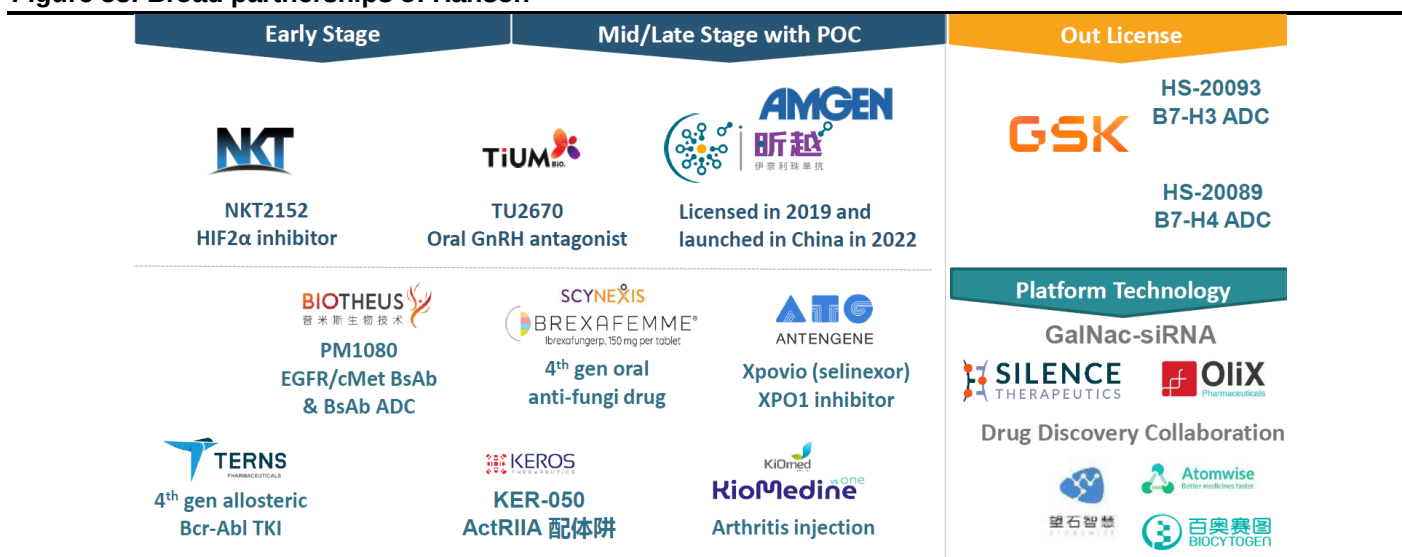
Solidifying the leading position through extensive global collaborations

In addition to its internal R&D efforts, Hansoh actively explores global collaboration opportunities to enhance its product pipeline through in-licensing partnerships, platform collaborations, and out-licensing agreements.

The Company has established various in-licensing partnerships with both overseas and domestic companies. Leveraging its R&D and commercialization capabilities, we expect Hansoh to become a top platform for biotech and biopharma companies seeking partnerships in China. We expect the Company to continue exploring in-licensing opportunities to expand its pipeline in areas such as oncology, metabolic diseases, CNS disorders, immunology, and kidney-related conditions.

Furthermore, Hansoh successfully out-licensed its internally-developed ADC assets to the global multinational corporation GSK through blockbuster deals in late 2023. In Oct 2023, GSK entered into an agreement with Hansoh to in-license the overseas rights of HS-20089 (B7-H4 ADC). This agreement involved an upfront payment of US\$85mn from GSK, with the potential for up to US\$1.485bn in milestone payments and tiered royalties. Subsequently, in Dec 2023, Hansoh entered into another blockbuster deal, granting the overseas rights of HS-20093 (B7-H3 ADC) to GSK. This transaction included an upfront payment of US\$185mn, up to US\$1.525bn milestone payments, in addition to future royalties. These external licensing deals not only validate Hansoh's R&D capabilities but also accelerate the global development of these drug candidates.

Figure 58: Broad partnerships of Hansoh



Source: Company data, CMBIGM

Figure 59: BD collaboration of Hansoh

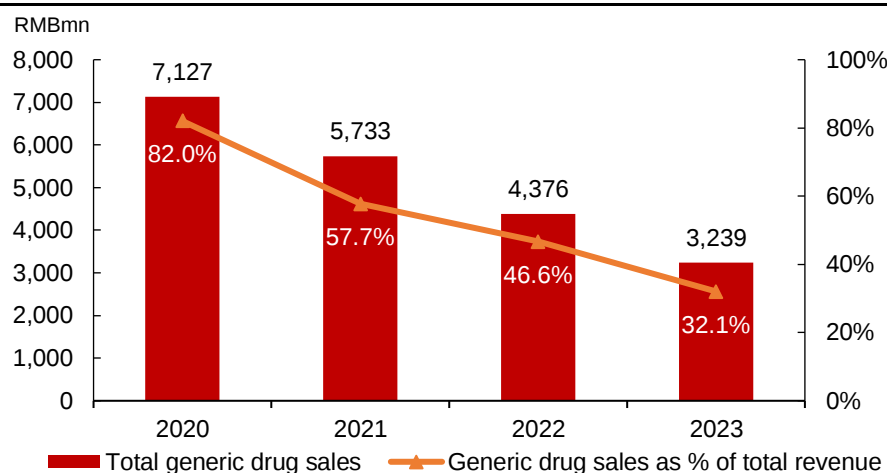
Date	Partner	Drug candidate	Target	Region	Payment	Link
License-out						
2023/12/20	GSK	HS-20093	B7-H3 ADC	ex-Greater China	US\$185mn upfront, US\$1.525bn milestone, royalties	Link
2023/10/20	GSK	HS-20089	B7-H4 ADC	ex-Greater China	US\$85mn upfront, US\$1.485bn milestone, royalties	Link
License-in / Platform collaboration						
2024/8/8	Lupeng Pharma	LP-168	BTki	Greater China	RMB729mn upfront + milestone, royalties	Link
2024/4/25	Qyuns Therapeutics (荃信生物)	QX004N	IL-23p19 mAb	Greater China	RMB75mn upfront, RMB1.032bn milestone, royalties	Link
2024/3/14	Biotheus (普米斯)	HS-20117/PM1080 related ADC	EGFR/cMet ADC	Global	RMB5.0bn upfront + milestone, royalties	Link
2023/8/11	Antengene (德琪医药)	selinexor	XPO1 inhibitor	Mainland China	Hansoh to pay RMB200mn upfront and RMB535mn milestone, Antengene to pay service fees	Link
2023/1/2	Biocytogen (百奥赛图)	Selected antibodies		Globe	Several 8-digit RMB upfront + milestone, single-digit royalties	Link
2022/11/15	Biotheus (普米斯)	HS-20117/PM1080	EGFR/cMet	Greater China	RMB50mn upfront, RMB1.418bn milestone, royalties	Link
2022/9/27	KiOmed Pharma	KiOmedinevsOne	Targeting osteoarthritis indication	Greater China	EUR66mn upfront + milestone, double-digit royalties	Link
2022/8/9	TiumBio	TU2670	non-peptide GnRH antagonist	Greater China	US\$6mn upfront, US\$164mn milestone, royalties	Link
2021/12/14	Keros Therapeutics	KER-050	TGF-β	Greater China	US\$20mn upfront, US\$1.705bn milestone, royalties	Link
2021/10/15	Silence Therapeutics	Silence mRNAi GOLD™ platform, three siRNA drug candidates	siRNA	Greater China	US\$16mn upfront, US\$1.3bn milestone, 10-15% royalties	Link
2021/10/12	OliX	GalNAc-asiRNA platform, asiRNA drug candidate	asiRNA	China	US\$6.5mn upfront, US\$450mn milestone	Link
2021/2/17	SCYNEXIS	Ibrexafungerp	triterpenoid antifungal	Greater China	US\$10mn upfront, milestone, royalties	Link
2020/7/29	Terns Pharmaceuticals (拓臻生物)	TRN-000632	BCR-ABL allosteric inhibitor	Greater China	RMB68mn upfront + milestone, royalties	Link
2020/4/24	NiKang Therapeutics	NKT-1992	Targeting anti-viral diseases	Greater China	US\$100mn upfront + milestone, royalties	Link
2019/9/12	Atomwise	Up to 11 undisclosed target proteins		--	US\$1.5bn tech access fees, option exercise fees, etc	Link
2019/5/24	Viela Bio (Horizon)	XINYUE/Inebilizumab	CD19 mAb	China	US\$220mn upfront + milestone, royalties	Link

Source: Company data, FDA labels, Pubmed, CMBIGM

Generic business has passed the worst time

Hansoh has experienced a sharp decline in sales of generic drugs over the past years, mainly due to price cuts from volume-based procurement (VBP). Thanks to the significant growth in innovative drugs, the proportion of revenue from generics has decreased from 82.0% in 2020 to 32.1% in 2023. We expect Hansoh's generic business to remain largely stable in the future given that most of the existing generic drugs have already experienced VBP.

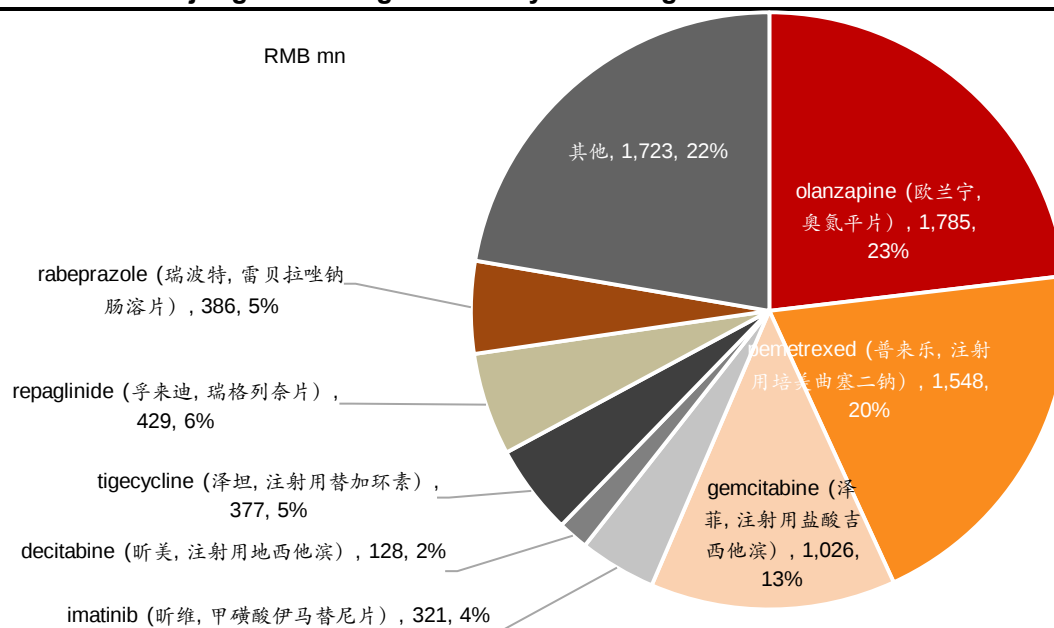
Figure 60: Hansoh's sales of generic drugs



Source: Company data, CMBIGM

Recall that in 2018, Hansoh's major generic drugs were olanzapine (奥氮平), pemetrexed (培美曲塞), gemcitabine (吉西他滨), repaglinide (瑞格列奈), tigecycline (替加环素), imatinib (伊马替尼), decitabine (地西他滨), and rabeprazole (雷贝拉唑). The eight generic drugs mentioned previously generated a revenue of RMB6.0bn in 2018, accounting for 78% of the company's total revenue for that year. As of now, all of these generic drugs have undergone the national Volume-Based Procurement (VBP) process, suggesting that the Company has already navigated the period of steep decline in generic drug sales. In the most recent Round 9 of national VBP, effective from Mar 2024 ([link](#)), lenalidomide (来那度胺), fulvestrant (氟维司群), and rabeprazole (雷贝拉唑) were included. However, Hansoh's bid for rabeprazole was not successful.

Figure 61: Hansoh's major generic drugs in 2018 by revenue generation



Source: Company data, CMBIGM

Figure 62: Hansoh's generic medicines included by national volume-based procurement

Round of national VBP	Drugs included	Effective date
Round 9 (国采第九批)	lenalidomide (来那度胺胶囊)、fulvestrant (氟维司群注射液)、 rabeprazole (雷贝拉唑钠肠溶片, Hansoh bid unsuccessful)	2024-03-01
Round 8 (国采第八批)		
Round 7 (国采第七批)	Erlotinib (盐酸厄洛替尼片)、micafungin (注射用米卡芬净钠)、afatinib (马来酸阿法替尼片)、sunitinib (苹果酸舒尼替尼胶囊)、lurasidone (盐酸鲁拉西酮片)、 tigecycline (注射用替加环素, Hansoh bid unsuccessful)	2022-11-29
Round 6 (国采第六批)		
Round 5 (国采第五批)	gemcitabine (注射用盐酸吉西他滨) 、linezolid (利奈唑胺葡萄糖注射液)、saxagliptin (沙格列汀片)、decitabine (注射用地西他滨)、dabigatran etexilate (达比加群酯胶囊)	2021-09-20
Round 4 (国采第四批)	repaglinide (瑞格列奈片) 、bortezomib (注射用硼替佐米)、empagliflozin (恩格列净片)	2021-04-28
Round 3 (国采第三批)	linezolid (利奈唑胺片)、prucalopride (琥珀酸普芦卡必利片)、cefdinir (头孢地尼胶囊)、vildagliptin (维格列汀片)、apixaban (阿哌沙班片)	2020-11-01
Round 2 (国采第二批)		
Round 1 extension (国采第一批扩围)	olanzapine (奥氮平片) 、 imatinib (甲磺酸伊马替尼片) 、 pemetrexed (注射用培美曲塞二钠)	2019-12-01
Round 1 (国采第一批 4+7)	olanzapine (奥氮平片) 、 imatinib (甲磺酸伊马替尼片) 、 pemetrexed (注射用培美曲塞二钠)	2019-03-20

Source: PharmCube, Company data, CMBIGM

Looking forward, we expect Hansoh's paliperidone (帕利哌酮缓释片), fosaprepitant dimeglumine (福沙匹坦双葡甲胺) and enzalutamide (恩扎卢胺软胶囊) could be subject to the risks of VBP. According to data from PharmCube, the total sales for these four drugs (including all original and generic brands) in sample hospitals were RMB963mn, RMB495mn, and RMB440mn respectively for the period of MAT2024Q1 (2Q23-1Q24). It is worth noting that only two agomelatine (阿戈美拉汀片) generics have passed bioequivalence assessment in China, suggesting that this drug is currently free from national VBP due to limited competition. In our view, given the relatively small scale of sales from these drugs, the potential impact of VBP on Hansoh's generic business will be marginal.

Figure 63: Hansoh's major commercial generic medicines by therapeutic areas

Sector	Drug name (Chinese)	Drug name (English)	Indications	Year of launch	NRDL	VB P	Comments
Oncology	普来乐 (注射用培美曲塞二钠)	pemetrexed disodium for injection	NSCLC, malignant pleural mesothelioma	2005	Y	Y	-
	普来坦 (恩扎卢胺软胶囊)	enzalutamide soft capsules	castration-resistant prostate cancer	2021	Y	N	First generic; six generics passed bioequivalence assessment; RMB440mn market size in sample hospitals (incl. all brands)
	昕维 (甲磺酸伊马替尼片)	imatinib mesylate tablets	MDS/MPD, ASM, DFSP, GIST	2013	Y	Y	-
	坦能 (注射用福沙匹坦双葡甲胺)	fosaprepitant dimeglumine for injection	chemotherapy-induced nausea and vomiting	2019	Y	N	First generic; five generics passed bioequivalence assessment; original drug not approved in China; RMB495mn market size in sample hospitals (incl. all brands)
	昕安 (来那度胺胶囊)	lenalidomide capsules	multiple myeloma	2021	Y	Y	Included in VBP, effective in Mar 2024
Metabolic diseases and others	瑞波特 (雷贝拉唑钠肠溶片)	sodium rabeprazole enteric-coated tablets	gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, etc.	2002	Y	Y	Included in VBP effective in Mar 2024, while Hansoh's bid was unsuccessful
	孚来迪 (瑞格列奈片)	repaglinide tablets	Type 2 diabetes	2000	Y	Y	-
	孚来瑞 (卡格列净片)	canagliflozin tablets	Type 2 diabetes	2019	Y	Y	-
	普诺安 (安立生坦片)	ambrisentan tablets	pulmonary arterial hypertension	2018	Y	Y	-
CNS diseases	阿美宁 (阿戈美拉汀片)	agomelatine tablets	adult depression	2014	Y	N	first generic; two generics passed bioequivalence assessment; RMB786mn market size in sample hospitals (incl. all brands)
	艾兰宁 (帕利哌酮缓释片)	paliperidone extended-release tablets	schizophrenia	2020	Y	N	first generic; four generics passed bioequivalence assessment; RMB963mn market size in sample hospitals (incl. all brands)
	欧兰宁 (奥氮平口服制剂)	olanzapine tablets	schizophrenia	2020	Y	Y	-
Anti-infective diseases	恒森 (注射用米卡芬净钠)	micalfungin sodium for injection	infections caused by aspergillus and candida	2018	Y	Y	-

Source: Company data, CMBIGM. Note: Number of generic drugs as of Aug 2024; not all of Hansoh's generic drugs are listed in the table.

Financial Analysis

In FY24E, we expect the Company's total revenue to increase 19% YoY, reaching RMB12.0bn. Of total revenue, sales from oncology is expected to increase 25% YoY to RMB7.7bn, accounting for 64% of total revenue. We anticipate Hansoh's total innovative drug sales to grow 37% YoY to RMB9.5bn in FY24E, accounting for 79% of the Company's total revenue. Meanwhile, we estimate the sales of generic drugs to decline 21% YoY to RMB2.5bn in FY24E. Excluding the impact of collaboration payment from GSK in FY23 and FY24, we expect the Company's organic revenue growth to reach 12%/ 14% YoY in FY24E/ 25E, respectively, and innovative drug sales to increase 29%/ 22% YoY in FY24E/ 25E, respectively. We expect the sales of aumolertinib to increase 23%/ 19%/ 17% YoY in FY24E/ 25E/ 26E, reaching RMB4.5bn/ 5.3bn/ 6.2bn, respectively.

Figure 64: Sales forecast by products

Revenue (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Oncology	7,697	7,291	8,253	10,194	11,181	12,321	13,785
Aumolertinib	4,472	5,316	6,194	7,200	7,648	7,914	8,162
Flumatinib	1,120	1,232	1,331	1,410	1,467	1,467	1,437
Selinexor	60	120	168	202	236	269	298
B7-H3 ADC	1,333	0	0	522	919	1,586	2,565
B7-H4 ADC	20	0	0	316	384	563	805
Other oncology drugs	692	623	561	544	528	522	517
CNS diseases	1,233	1,201	1,225	1,275	1,326	1,387	1,433
Inebilizumab	165	239	311	389	467	537	590
Other CNS drugs	1,068	962	914	886	860	851	842
Anti-infective diseases	1,655	2,003	2,390	2,768	3,106	3,347	3,338
Morinidazole	430	430	421	413	405	397	389
HS-10234	1,065	1,385	1,731	2,077	2,388	2,627	2,627
Ibrexafungerp	50	90	144	187	225	236	236
Other anti-infective drugs	110	99	94	91	88	87	86
Metabolic disease and others	1,449	1,696	1,911	2,417	3,206	4,151	5,080
Polyethylene glycol loxenatide	697	809	874	1,005	1,121	1,219	1,169
Pegol-Sihematide	100	300	480	720	1,008	1,310	1,572
HS-20094 (GLP-1/GIP)				152	553	1,102	1,825
Other drugs	652	587	557	541	524	519	514
Other pipeline innovative drugs	0	0	100	150	250	350	500
Total revenue	12,034	12,191	13,878	16,804	19,069	21,556	24,136
YoY	19%	1%	14%	21%	13%	13%	12%
 Total innovative drug sales	 9,512	 9,921	 11,753	 14,742	 17,069	 19,577	 22,176
YoY	37%	4%	18%	25%	16%	15%	13%
% of total revenue	79%	81%	85%	88%	90%	91%	92%
 Total generic drug sales	 2,522	 2,270	 2,125	 2,062	 2,000	 1,980	 1,960
YoY	-21%	-10%	-6%	-3%	-3%	-1%	-1%
% of total revenue	21%	19%	15%	12%	10%	9%	8%

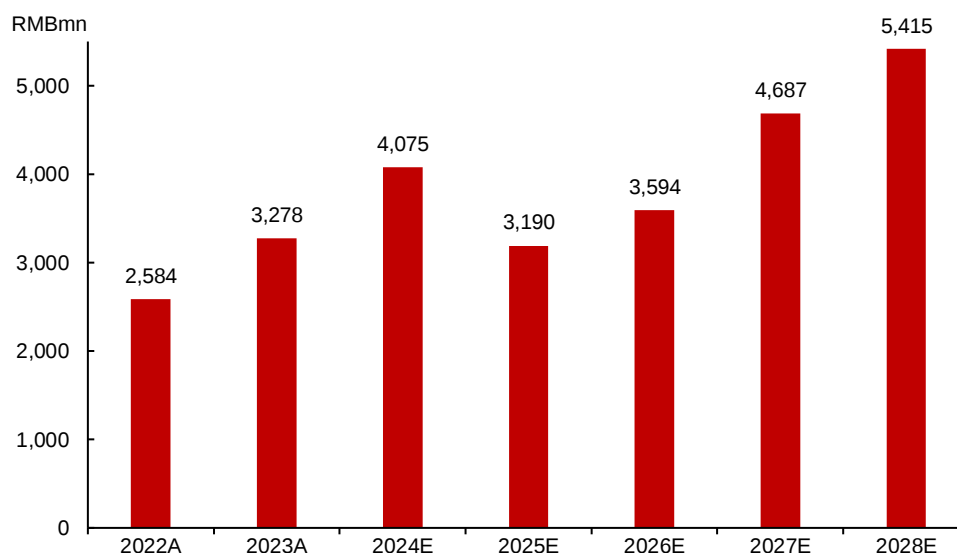
Source: CMBIGM.

In FY22/23, the Company generated attributable net profit of RMB2.6bn/ 3.3bn. Going forward, we expect the Company's attributable net profit to increase 24% and decrease 22% YoY in FY24E and FY25E to RMB4.1bn/ 3.2bn, respectively. The fluctuation in net profit will be mainly due to impact from BD income.

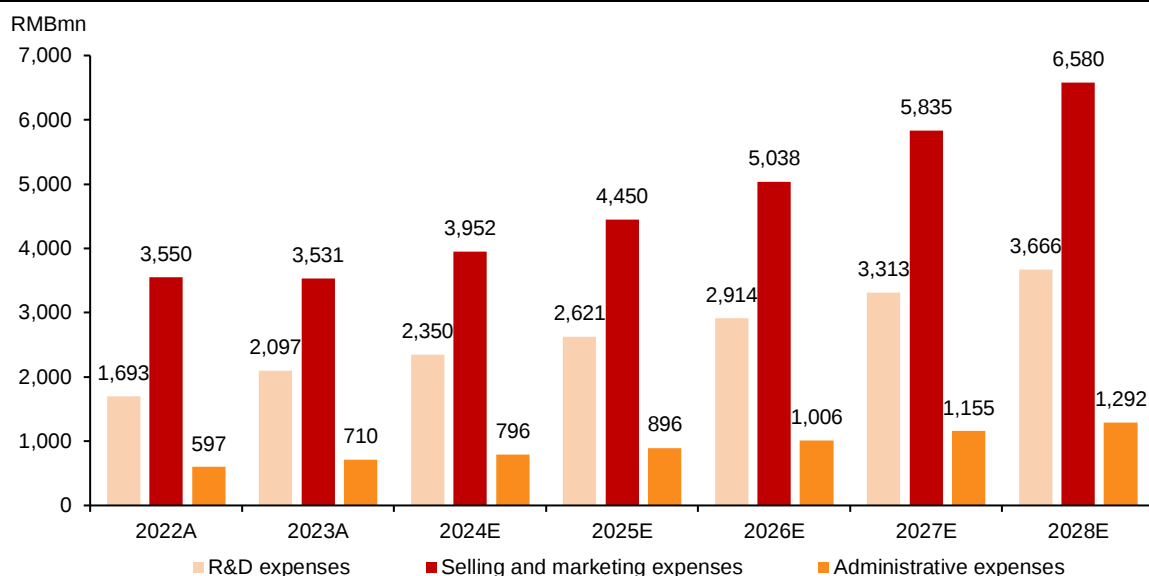
Figure 65: P&L forecasts

YE Dec 31 (RMB mn)	2022A	2023E	2024E	2025E	2026E	2027E	2028E
Revenue	9,382	10,104	12,034	12,191	13,878	16,804	19,069
YoY	-6%	8%	19%	1%	14%	21%	13%
Cost of sales	(867)	(1,031)	(1,175)	(1,341)	(1,527)	(1,778)	(2,016)
% of revenue	9%	10%	10%	11%	11%	11%	11%
Gross profit	8,515	9,073	10,859	10,850	12,352	15,026	17,053
GPM	91%	90%	90%	89%	89%	89%	89%
R&D expenses	(1,693)	(2,097)	(2,350)	(2,621)	(2,914)	(3,313)	(3,666)
% of revenue	18%	21%	20%	22%	21%	20%	19%
Selling and marketing expenses	(3,550)	(3,531)	(3,952)	(4,450)	(5,038)	(5,835)	(6,580)
% of revenue	38%	35%	33%	37%	36%	35%	35%
Administrative expenses	(597)	(710)	(796)	(896)	(1,006)	(1,155)	(1,292)
% of revenue	6%	7%	7%	7%	7%	7%	7%
Profit/(loss) before tax	2,948	3,766	4,683	3,665	4,129	5,385	6,223
% of revenue	31%	37%	39%	30%	30%	32%	33%
Income tax expense	-365	-489	-608	-476	-536	-699	-807
Attributable net profit/(loss)	2,584	3,278	4,075	3,190	3,594	4,687	5,415
YoY	-5%	27%	24%	-22%	13%	30%	16%
NMP	28%	32%	34%	26%	26%	28%	28%

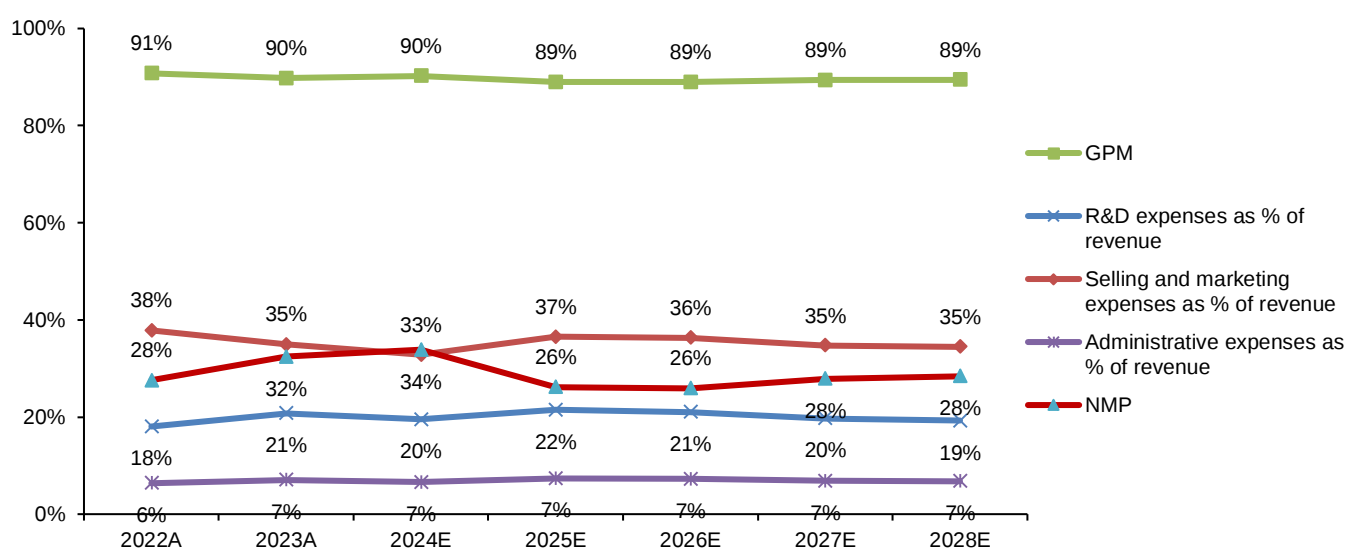
Source: Company data, CMBIGM estimates

Figure 66: Attributable net profit forecasts

Source: Company data, CMBIGM estimates

Figure 67: Operating expenses forecast

Source: Company data, CMBIGM estimates

Figure 68: Operating expenses forecast (as % of revenue)

Source: Company data, CMBIGM estimates

Valuation

We derived our 12-year DCF-based price target of HK\$22.06 based on the assumptions of 8.67% WACC and 3.0% terminal growth rate.

Figure 69: DCF valuation

DCF Valuation (in RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	3,942	3,063	3,574	4,902	5,694	6,668	7,858	8,833	9,484	9,874	10,147	10,154
Tax rate	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%
EBIT*(1-tax rate)	3,430	2,666	3,110	4,266	4,955	5,803	6,838	7,687	8,253	8,593	8,830	8,836
+ D&A	372	358	345	334	324	315	306	299	292	286	281	276
- Change in working capital	-716	-37	-530	-921	-681	-727	-723	-317	58	181	203	245
- Capex	-400	-200	-200	-200	-200	-200	-200	-200	-200	-200	-200	-200
FCFF	2,686	2,787	2,725	3,479	4,398	5,190	6,222	7,469	8,403	8,860	9,114	9,157
Terminal value												166,495
Terminal growth rate	3.0%											
WACC	8.67%											
Cost of Equity	11.5%											
Cost of Debt	4.0%											
Equity Beta	0.90											
Risk Free Rate	2.5%											
Market Risk Premium	10.0%											
Target Debt to Asset ratio	35.0%											
Effective Corporate Tax Rate	15.0%											
Present value of enterprise (RMB mn)	99,118											
Net debt (RMB mn)	-20,036											
Equity value (RMB mn)	119,154											
No. of shares (mn)	5,936											
DCF per shares (RMB)	20.07											
DCF per share (HK\$)	22.06											

Source: CMBIGM estimates

Figure 70: Sensitivity analysis

		WACC				
		7.67%	8.17%	8.67%	9.17%	9.67%
Terminal growth	4.0%	30.99	27.43	24.63	22.38	20.54
	3.5%	28.53	25.59	23.22	21.28	19.66
	3.0%	26.59	24.10	22.06	20.35	18.91
	2.5%	25.03	22.88	21.09	19.57	18.27
	2.0%	23.75	21.86	20.26	18.89	17.71

Source: Company data, CMBIGM estimates

Figure 71: CMBIGM vs Consensus

RMB mn	CMBI			Consensus			Diff (%)		
	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E
Revenue	12,034	12,191	13,878	11,897	12,414	13,939	1%	-2%	0%
Gross profit	10,859	10,850	12,352	10,729	11,166	12,531	1%	-3%	-1%
Operating profit	4,683	3,665	4,129	3,889	3,783	4,307	20%	-3%	-4%
Attributable net profit	4,075	3,190	3,594	3,794	3,717	4,263	7%	-14%	-16%
EPS (RMB)	0.69	0.54	0.61	0.63	0.63	0.72	9%	-15%	-16%
Gross margin	90.24%	89.00%	89.00%	90.18%	89.95%	89.90%	+0.06 ppt	-0.95 ppt	-0.90 ppt
Operating margin	38.91%	30.06%	29.75%	32.69%	30.47%	30.90%	+6.22 ppt	-0.41 ppt	-1.15 ppt
Net margin	33.86%	26.16%	25.89%	31.89%	29.94%	30.58%	+1.97 ppt	-3.78 ppt	-4.69 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Appendix

Figure 72: Major shareholders

Shareholder	% of stake
Sunrise Trust Trustee (owned by Ms. Zhong Huijuan and Ms. Sun Yuan)	65.70%
JQC International Limited (owned by Cen Junda)	16.00%
FMR LLC	3.47%
BlackRock	0.71%
Vanguard	0.66%
FIL Ltd	0.64%

Source: Bloomberg, CMBIGM. Note: Data retrieved from Bloomberg on 26 Aug 2024.

Figure 73: Management profile

Name	Position
Ms. ZHONG Huijuan (钟慧娟)	Chairlady of the Board, CEO, Executive Director
Ms. SUN Yuan (孙远)	Executive Director, responsible for providing guidance on R&D strategies, business development, investment strategies and the scientific development
Dr. LYU Aifeng (吕爱锋)	Executive Director, Chairman of the ESG Committee and a member of the Strategy and Development Committee
Dr. LEE Chih-Hung (李志宏)	Chief of Science Officer
Dr. SUN Weiyong (孙伟勇)	Chief Commercial Officer
Mr. XU Chuanhe (徐传合)	Senior Vice President, responsible for matters related to business management
Mr. HU Min (胡旻)	Chief Financial Officer
Mr. LU Yifeng (陆一峰)	Vice President, responsible for production operations and import and export business of APIs

Source: Company data, CMBIGM

Financial Summary

INCOME STATEMENT	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Revenue	9,935	9,382	10,104	12,034	12,191	13,878
Cost of goods sold	(870)	(867)	(1,031)	(1,175)	(1,341)	(1,527)
Gross profit	9,065	8,515	9,073	10,859	10,850	12,352
Selling expense	(3,428)	(3,550)	(3,531)	(3,952)	(4,450)	(5,038)
Admin expense	(943)	(597)	(710)	(796)	(896)	(1,006)
R&D expense	(1,797)	(1,693)	(2,097)	(2,350)	(2,621)	(2,914)
Other income	393	449	1,125	965	785	739
Other gains/(losses)	63	(117)	(27)	0	0	0
Net Interest income/(expense)	(53)	(58)	(67)	(44)	(3)	(3)
Pre-tax profit	3,300	2,948	3,766	4,683	3,665	4,129
Income tax	(587)	(365)	(489)	(608)	(476)	(536)
After tax profit	2,713	2,584	3,278	4,075	3,190	3,594
Net profit	2,713	2,584	3,278	4,075	3,190	3,594

BALANCE SHEET	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Current assets	23,179	25,832	28,883	27,377	29,640	32,156
Cash & equivalents	14,702	17,615	22,435	20,156	22,351	24,302
Account receivables	3,676	3,578	3,214	3,979	3,964	4,437
Inventories	410	448	576	583	666	758
Prepayment	160	182	236	236	236	236
Financial assets at FVTPL	2,357	2,544	512	512	512	512
Other current assets	1,874	1,464	1,910	1,910	1,910	1,910
Non-current assets	3,981	4,170	4,156	4,184	4,026	3,880
PP&E	3,225	3,196	3,045	3,104	2,976	2,862
Right-of-use assets	251	254	235	214	193	172
Intangibles	17	33	177	167	157	147
Other non-current assets	488	687	699	699	699	699
Total assets	27,160	30,002	33,039	31,561	33,665	36,036
Current liabilities	3,024	2,620	6,863	2,736	2,767	2,802
Short-term borrowings	0	0	0	0	0	0
Account payables	248	222	164	220	251	286
Other current liabilities	134	91	4,269	86	86	86
Lease liabilities	10	16	16	16	16	16
Contract liabilities	22	25	38	38	38	38
Accrued expenses	2,609	2,266	2,376	2,376	2,376	2,376
Non-current liabilities	4,108	4,735	381	381	381	381
Convertible bonds	3,743	4,283	40	40	40	40
Deferred income	267	351	255	255	255	255
Other non-current liabilities	98	102	87	87	87	87
Total liabilities	7,131	7,355	7,244	3,117	3,148	3,183
Share capital	0	0	0	0	0	0
Other reserves	20,029	22,647	25,795	28,444	30,517	32,853
Total shareholders equity	20,029	22,647	25,795	28,444	30,517	32,853
Total equity and liabilities	27,160	30,002	33,039	31,561	33,665	36,036

CASH FLOW	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	3,300	2,948	3,766	4,683	3,665	4,129
Depreciation & amortization	257	316	335	341	327	315
Tax paid	(319)	(324)	(590)	(608)	(476)	(536)
Change in working capital	(428)	(306)	257	(716)	(37)	(530)
Others	(232)	107	(652)	(610)	(471)	(425)
Net cash from operations	2,577	2,741	3,116	3,090	3,009	2,953
Investing						
Capital expenditure	(460)	(273)	(220)	(400)	(200)	(200)
Acquisition of subsidiaries/ investments	(357)	(186)	(239)	0	0	0
Net proceeds from disposal of short-term investments	(1,481)	(5,411)	1,418	685	505	459
Others	40	(65)	114	0	0	0
Net cash from investing	(2,259)	(5,935)	1,074	285	305	259
Financing						
Dividend paid	(381)	(712)	(652)	(1,426)	(1,116)	(1,258)
Net borrowings	15	0	0	0	0	0
Proceeds from share issues	(58)	(77)	(115)	0	0	0
Others	3,841	(29)	13	(4,227)	(3)	(3)
Net cash from financing	3,417	(818)	(754)	(5,654)	(1,119)	(1,261)
Net change in cash						
Cash at the beginning of the year	3,063	6,719	2,666	5,981	3,702	5,897
Exchange difference	(79)	(41)	(122)	0	0	0
Cash at the end of the year	6,719	2,666	5,981	3,702	5,897	7,848

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

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