Simcere Pharmaceutical Group (2096 HK)

Transitioning from generic to innovative

- **China-based pharmaceutical company with global presence.** Simcere Pharmaceutical Group Limited ("Simcere") was listed on the NYSE in 2007, as the first Chinese bio and chemical pharmaceutical company listed on the NYSE, and completed privatization in 2013. Simcere is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, leveraging its leading manufacturing and commercial capabilities.
- **Diversified product portfolio.** Simcere has established a diversified product portfolio comprising five products for the treatment of oncology diseases, three products for the treatment of central nervous system diseases, five products for the treatment of autoimmune diseases, three products for the treatment of cardiovascular diseases, 16 products for the treatment of bacterial or virus-related infectious diseases and a number of products for the treatment of other diseases. Core products include Endostar (an innovative biological drug for oncology), Iremod (an innovative chemical drug for auto-immune diseases), Bicun (a CNS drug), etc.
- **Rich innovative drug pipelines.** Simcere has established three R&D centres in Nanjing (the Jiangsu Province), Shanghai and Boston (the US), respectively. Capitalizing on its proven track record of in-house R&D capacity and solid collaboration relationships with leading domestic and international pharmaceutical companies, Simcere has established a comprehensive innovative portfolio with nearly 50 candidates in different stages of development, including small molecule pharmaceuticals, large molecule pharmaceuticals and CAR T-cell therapies, among which over 10 product candidates were at clinical stage, had submitted NDA or had obtained NDA pending market launch.
- **Potential blockbusters started commercialization in 2020.** Simcere launched two innovative drugs, Orencia (abatacept injection) and Sanbexin (edaravone and dexborneol concentrated solution for injection) in 2H20, both of which are potential blockbusters. Sanbexin was recently added into the NRDL, effective from Mar 2021. In addition, KN035, a potentially first-to-market subcutaneously injectable anti-PD-L1 monoclonal antibody worldwide, filed NDA to the NMPA for treatment of MSI-H solid tumors in Dec 2020.
- **Initiate at BUY with TP of HK$13.84**. We expect Simcere's attributable net profit to grow from RMB1,004mn in 2019 to RMB1,453mn in 2022E, representing a CAGR of 13.1%. To factor in the potential contribution from innovative drug pipelines, we use DCF model in valuing the Company. We derive our target price of HK$13.84 based on a 10-year DCF valuation (WACC: 10.4%, terminal growth rate: 2.0%).

Earnings Summary

(YE 31 Dec)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue (RMB mn)	4,514	5,037	4,554	6,458	8,164
YoY growth (%)	17	12	(10)	42	26
Net income (RMB mn)	734	1,004	684	1,150	1,453
YoY growth (%)	109	37	(32)	68	26
P/E ratio	N/A	N/A	29.1	17.3	13.7
EPS (RMB)	N/A	N/A	0.26	0.44	0.56
Consensus EPS (RMB)	N/A	N/A	0.22	0.49	0.62
ROE (%)	46.9	67.8	13.6	19.4	20.5
Net gearing (%)	56	155	Net cash	Net cash	Net cash

Source: Company data, CMBIS estimates

BUY (Initiation)

Target Price	HK$13.84
Up/Downside	+59.07%
Current Price	HK$8.70

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Mkt. Cap. (HK$ mn)	22,695
Avg. 3mths t/o (HK$ mn)	N/A
52W High/Low (HK$)	11.68/7.65
Total Issued Shares (mn)	2,609

Source: Bloomberg

Shareholding Structure

Simcere Pharmaceutical Holding	45.85%
Artking Global	23.26%
Fortune Fountain Investment	4.64%
Premier Praise	4.41%
Excel Good Groupl	4.30%
King View Development Internationa	2.25%
Excel Management	2.13%
Free float	13.16%

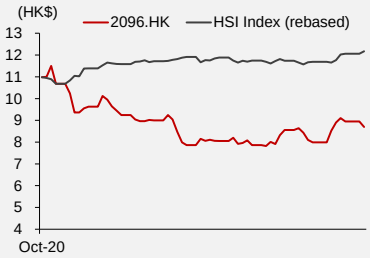
Source: HKEx, Bloomberg

Share performance

	Absolute	Relative
1-mth	11.0%	9.0%
3-mth	N/A	N/A
6-mth	N/A	N/A

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: KPMG
Web-site: www.simcere.com

Contents

Investment Thesis

Simcere has a diversified and leading innovative product portfolio in its strategically focused therapeutic areas, including, (i) oncology, (ii) central nervous system diseases and (iii) autoimmune diseases. The Company is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, leveraging its leading manufacturing and commercial capabilities.

Diversified product portfolio

Simcere has established a diversified product portfolio comprising five products for the treatment of oncology diseases, two products for the treatment of central nervous system diseases, five products for the treatment of autoimmune diseases, three products for the treatment of cardiovascular diseases, 16 products for the treatment of bacterial or virus-related infectious diseases and a number of products for the treatment of other diseases. The Company's existing portfolio comprises both its pharmaceutical products that the Company manufactures in-house and third-party pharmaceutical products from reputable pharmaceutical companies that the Company sells and/or promotes. The Company also manufactures and sells a number of APIs, such as diosmectite (蒙脱石).

The Company's oncology product portfolio currently comprises five products, including four major products: Endostar, Jepaso, Jiebaili and Sinofuan. In 2017, 2018, and 2019, sales of the oncology products were RMB1,004.8mn, RMB1,279.7mn, and RMB1,568.9mn, respectively, accounting for 25.9%, 28.4%, and 31.0% of revenue from sales of pharmaceutical products.

The Company's CNS product portfolio includes two products, including one of its major products, Bicun. In 2017, 2018, and 2019, the Company's sales of central nervous system products were RMB1,276.1mn, RMB1,202.0mn, and RMB936.9mn, respectively, accounting for 33.3%, 27.9%, and 19.5% of revenue from sales of pharmaceutical products.

The Company's autoimmune product portfolio contains five products, including two of its major products, Iremod and Yingtaiqing. In 2017, 2018, and 2019, the Company's sales of autoimmune products were RMB423.2mn, RMB537.8mn, and RMB813.8mn, respectively, accounting for 11.0%, 12.5%, and 17.0% of revenue from sales of pharmaceutical products.

Expanding innovative drug pipeline

The Company has established three R&D centres in Nanjing (the Jiangsu Province), Shanghai and Boston (the US), respectively. As of 30 Jun 2020, the Company's R&D department consisted of 756 full-time employees, 331 of whom held master's degrees and 116 held Ph.D. degrees. Over 10% of the Company's employees in R&D department are scientists or former R&D personnel from overseas well-known pharmaceutical companies or universities. In 2017, 2018, and 2019, the Company's research and development expenses were RMB212.3mn, RMB447.1mn, and RMB716.4mn, representing 5.5%, 9.9%, and 14.2% of the Company's total revenue, respectively.

Capitalizing on its proven track record of in-house development together with a global vision, the Company has successfully established collaboration relationships with leading domestic and international pharmaceutical companies and biotechnology companies, securing exclusive development and commercialization rights in China. The Company had nearly 50 innovative product candidates in different stages of development, including small molecule pharmaceuticals, large molecule pharmaceuticals and CAR T-cell therapies, among which over 10 product candidates were at clinical stage, had submitted NDA or had obtained NDA pending market launch.

The Company entered into a tripartite collaboration agreement with Jiangsu Alphamab and 3D Medicines Beijing, together with a separate marketing and promotion agreement with 3D Medicines Beijing, on 30 Mar 2020, in respect of KN035. KN035 is potentially the first subcutaneously injectable anti-PD-L1 monoclonal antibody. The Company's collaboration partners are currently conducting phase II clinical trials of KN035 for dMMR/MSI-H colorectal carcinoma and other advanced solid tumors and phase III clinical trials for advanced BTC in mainland China as well as phase I clinical trials in the US and Japan. KN035 has submitted NDA to the NMPA for treatment of MSI-H solid tumors in Dec 2020 and is expected to be launched in the PRC market in 2021E.

Initiate at BUY with TP of HK$13.84

We expect Simcere's attributable net profit to grow from RMB1,004mn in 2019 to RMB1,453mn in 2022E, representing a CAGR of 13.1%. To factor in the potential contribution from innovative drug pipelines, we use DCF model in valuing the Company. We derive our target price of HK$13.84 based on a 10-year DCF valuation (WACC: 10.4%, terminal growth rate: 2.0%).

Investment risks

1) If the Company's products are removed from NRDL, Simcere's sales, profitability and business prospects could be materially affected.

2) The prices of certain of Simcere's products may decrease due to pricing regulation, competition and other factors.

3) Development of new products, in particular innovative drugs, is time-consuming and costly and the outcome is uncertain. Failure to develop and commercialize new products may affect Simcere's business prospects adversely.

Company Overview

China-based pharmaceutical company with global presence

Simcere was listed on the NYSE in 2007, as the first Chinese bio and chemical pharmaceutical company listed on the NYSE. It has made considerable progress over 19 years of operating history as a dynamic pharmaceutical company. The Company subsequently completed privatization in 2013.

The Company is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, leveraging its leading manufacturing and commercial capabilities. The Company has a diversified and leading innovative product portfolio in its strategically focused therapeutic areas, including, (i) oncology (including cell therapy), (ii) central nervous system diseases and (iii) autoimmune diseases. Together, these therapeutic areas accounted for 24.7% of the pharmaceutical market in China in terms of sales revenue in 2019 and grew faster than the overall pharmaceutical market in China from 2015 to 2019, a trend which is expected to continue overall in the near future, according to F&S.

Figure 1: Development milestone of Simcere

Year	Event
1995	Jiangsu Simcere, one of the Company's principal operating subsidiaries, was established primarily engaging in the sales, marketing and distribution of pharmaceuticals.
2001	The Group acquired a controlling interest in Hainan Simcere and as a result, acquired manufacturing capabilities of pharmaceuticals.
	The Group started to build its own research and development team.
2003	The Group acquired the entire equity interest in Simcere Pharmaceutical, which further enriched its product portfolio and production capabilities.
	The Group established postdoctoral research station (博士后科研工作站).
2006	Assure Ahead, an investment holding company controlled by Hony Capital II, L.P. completed its strategic investment in the Group.
	The Group acquired a controlling interest in Shandong Simcere.
2007	Simcere Investments was listed on the NYSE on April 20, 2007, making it the first bio and chemical pharmaceutical company in China to be listed on the NYSE.
2013	Simcere Investments completed its privatization and ceased trading on the NYSE.
2014	The Group completed internal restructuring and the spin-off of the BioSciKin Business, thereby further refining its strategic focus.
2015	The Ministry of Science and Technology of the People's Republic of China approved the Group's establishment of the National Key Laboratory of Translational Medicine and Innovative Pharmaceuticals (转化医学与创新药物国家重点实验室).
	The Company was incorporated in Hong Kong.
2019	The Group established Simcere Boston R&D Center.

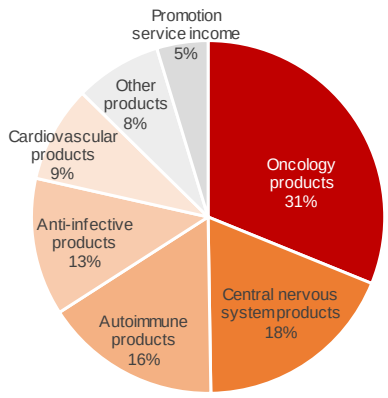
Source: Company data, CMBIS

Diversified product portfolio

Simcere's total revenue increased from RMB3,867.9mn in 2017 to RMB5,036.7mn in 2019, representing a CAGR of 14.1%. Net profit increased from RMB350.4mn in 2017 to RMB1,003.6mn in 2019, representing a CAGR of 69.2%.

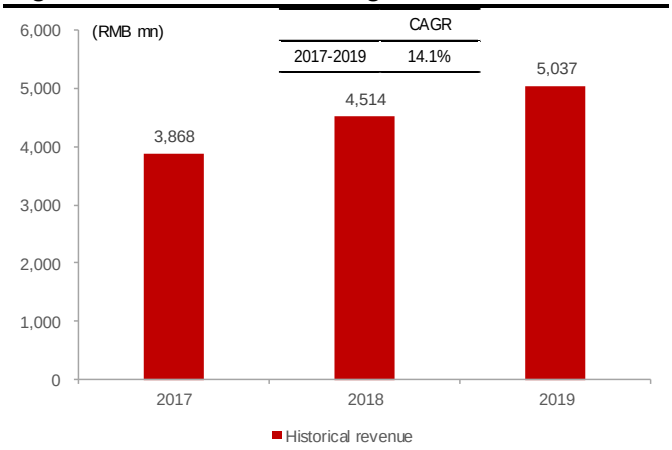
With continuous growth over the years, the Company has established a diversified product portfolio comprising five products for the treatment of oncology diseases, three products for the treatment of central nervous system diseases, five products for the treatment of autoimmune diseases, three products for the treatment of cardiovascular diseases, 16 products for the treatment of bacterial or virus-related infectious diseases and a number of products for the treatment of other diseases. The Company's existing portfolio comprises both its pharmaceutical products that the Company manufactures in-house and third-party pharmaceutical products from reputable pharmaceutical companies that the Company sells and/or promotes. The Company also manufactures and sells a number of APIs, such as diosmectite (蒙脱石).

Figure 2: Revenue breakdown of Simcere (2019A)



Source: Company data, CMBIS

Figure 3: Historical revenue growth of Simcere



Source: Company data, CMBIS

The Company's category I innovative pharmaceuticals, namely, Endostar (recombinant human endostatin injection, the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide) and Iremod (iguratimod tablets, a small molecule DMARD, the first iguratimod pharmaceutical product approved for sale in the world), contributed 21.4%, 25.5%, and 32.9% of total revenue in 2017, 2018, and 2019, respectively.

The Company expects to launch in 2020 and 2021 the sales and/or promotion of innovative near-commercial products including edaravone and dexborneol concentrated solution for injection (Sanbexin™) (an edaravone compound with significantly higher efficacy than edaravone monotherapy in patients with ischemic stroke) and KN035 (Envafolimab) (a subcutaneously injectable PD-L1 inhibitor), both of which are category I innovative pharmaceuticals, as well as Orencia (abatacept injection) (a CTLA4-Fc fusion protein for the treatment of moderate to severe rheumatoid arthritis), which is an imported innovative pharmaceutical.

Figure 4: Core products of Simcere

Therapeutic area	Major product	Classification	Indication(s)	Year of approval for sales in China	OTC/prescription pharmaceutical	Status of consistency evaluation	Specifications	NRDL	National Essential Drug List
Oncology:	Endostar (recombinant human endostatin injection)	Category I innovative pharmaceutical	NSCLC	2005	Prescription	N/A	15mg/2.4×105U/ 3ml per pre-filled syringe	Yes, Part B	No
	Jepaso (nedaplatin for injection)	First-to-market generic pharmaceutical	Solid tumors	2003	Prescription	Application filed	10mg per vial	Yes, Part B	No
	Jiebaili (pemetrexed disodium for injection)	Generic pharmaceutical	Non-squamous NSCLC; pleural mesothelioma	2009	Prescription	Application filed	0.1g/0.2g/0.5g per vial	Yes, Part B	Yes
	Sinofuan (5-fluorouracil implants)	New formulation drug	Digestive system tumors	2003	Prescription	N/A	0.1g per vial	No	No
Central nervous system diseases:	Bicun (edaravone injection)	First-to-market generic pharmaceutical	Cerebral infarction	2003	Prescription	Application filed	5ml:10mg/ 20ml:30mg per ampoule	No	No
	Sanbexin (Eedaravone and dexborneol concentrated solution injection; 依达拉奉右莰醇注射用浓溶液)	Category I innovative pharmaceutical	Cerebral infarction	2020	Prescription	N/A	5ml:10mg+2.5mg per ampoule	Yes	No
Autoimmune diseases:	Iremod (iguratimod tablets)	Category I innovative pharmaceutical	Active rheumatoid arthritis	2011	Prescription	N/A	25mg per pill	Yes, Part B	No
	Yingtaiqing (diclofenac sodium sustainedrelease capsules/ gel)	First-to-market generic pharmaceutical (for capsules)/ Generic pharmaceutical (for gel)	Pain relief	2005 (for gel)	Prescription (for capsules)/OTC (for gel)	-	50mg per pill (capsules)/0.15g/ 0.20g/0.05g per tube (gel)	Yes, Part A (for capsules)/No (for gel)	Yes (for capsules)/No (for gel)
	Orencia (Abatacept injection)	Category I innovative pharmaceutical	Moderate to severe active rheumatoid arthritis.	2020	Prescription	N/A	125mg (0.95 ml) per pre-filled syringe	No	No
Cardiovascular diseases:	Softan (rosuvastatin calcium tablets)	Generic pharmaceutical	High cholesterol	2011	Prescription	Passed in October 2018 (10mg) and March 2019 (5mg)	5mg/10mg per pill	Yes, Part B	Yes
Anti-infectives:	Newanti (biapenem for injection)	First-to-market generic pharmaceutical	Bacterial infections	2008	Prescription	Application filed	0.3g per vial	Yes, Part B	No
	ZAILIN (amoxicillin granules/dispersible tablets/capsules)	Generic pharmaceutical	Bacterial infections	1993 (for granules)/ 2002 (for tablets)/1996 (0.25g) (for capsules)	Prescription	Passed in September 2019 (for granules)/ Passed in November 2019 (for capsules)	0.125g per pack (granules)/ 0.25g per pill (tablets)/ 0.25g per pill (capsules)	Yes, Part A	Yes

Source: Company data, CMBIS
Note: The Yingtaiqing-branded sustained-release capsules are produced by and sourced from CPU Pharma.

Rich innovative drug pipelines

The Company has been continuously increasing investment in R&D over the years. As of 30 Jun 2020, the Company's R&D department consisted of 756 full-time employees, 331 of whom held master's degrees and 116 held Ph.D. degrees.

The Company has established three R&D centers in Nanjing (the Jiangsu Province), Shanghai and Boston (the US), respectively. With the approval of the Ministry of Science and Technology, it has also established a national key laboratory of translational medicine and innovative pharmaceuticals (转化医学与创新药物国家重点实验室). In 2017, 2018 and 2019, the research and development costs accounted for 5.5%, 9.9% and 14.2%, respectively, of total revenue.

Capitalizing on its proven track record of in-house development together with a global vision, the Company's business development team stays keen on market developments and actively pursues potential collaboration opportunities. The Company has successfully established collaboration relationships with leading domestic and international pharmaceutical companies and biotechnology companies, securing exclusive development and commercialization rights in China. Its vigorous in-house R&D efforts and extensive R&D collaborations have translated into a robust pipeline of product candidates.

The Company had nearly 50 innovative product candidates in different stages of development, including small molecule pharmaceuticals, large molecule pharmaceuticals and CAR T-cell therapies, among which over 10 product candidates were at clinical stage, had submitted NDA or had obtained NDA pending market launch.

Figure 5: Key innovative drug pipelines of Simcere

Therapeutic area	Product candidate	Classification	Target/ mechanism	Intended indication(s)	Collaboration with R&D partner(s)	Status
Oncology	Sevacizumab (Humanized anti-VEGF monoclonal antibody for injection) (赛伐珠单抗(注射用人源化抗VEGF单克隆抗体))	Biologics	VEGF	Ovarian cancer	Collaboration with Apexigen	Phase I clinical trials
	CD19 CAR T-cell therapy (Indication 1)	Biologics – cell therapy	CD19	r/r CD19 positive non-Hodgkin's lymphoma	Collaboration with Immunochina	IND approval obtained
	CD19 CAR T-cell therapy (Indication 2)	Biologics – cell therapy	CD19	r/r CD19 positive B-cell acute lymphoblastic leukemia	Collaboration with Immunochina	IND approval obtained
	BCMA CAR T-cell therapy	Biologics – cell therapy	BCMA	r/r multiple myeloma	Collaboration with PREGENE	IND approval obtained
	SIM - 201	Small molecule drug	NTRK	Solid tumors	N/A	IND approval obtained
	Trilaciclib	Small molecule drug	CDK4/6	Chemotherapy-induced myelosuppression	Collaboration with GI Therapeutics	Preparation for IND application
	SIM - 325	Biologics – cell therapy	HPV-16 E6 oncoprotein	Cervical cancer, head and neck cancer	Collaboration with TCRCure Beijing	Pre-clinical
	Subcutaneous PD-L1 single domain antibody combination therapy – 1	Biologics	PD-L1 + VEGF	Solid tumors	Collaboration with Jiangsu Alphamab and 3D Medicines Beijing	Pre-clinical
	Subcutaneous PD-L1 single domain antibody combination therapy – 2	Biologics	PD-L1 + multi-targets RTK	Solid tumors	Collaboration with Jiangsu Alphamab and 3D Medicines Beijing	Pre-clinical
	SIM-323	Biologics	CD80+IL2	Solid tumors	Collaboration with GI Innovation	Pre-clinical
	SIM - 235	Biologics	TNFR2	Solid tumors	N/A	Pre-clinical
	SIM - 237	Biologics	PD-L1 and IL15 receptor	Solid tumors	N/A	Pre-clinical
	SIM - 200	Small molecule drug	EGFR	NSCLC	N/A	Pre-clinical
	SIM - 236	Biologics	PD-L1+TGFβR	Solid tumors	N/A	Pre-clinical
	SIM - 203 - 1	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical
	SIM - 203 - 2	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical
	SIM - 203 - 3	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical
CNS	Edaravone and dexborneol concentrated solution for injection (依达拉奉右莰醇注射用浓溶液)	Small molecule drug	Free radicals and inflammatory cytokines	Acute ischemic stroke	N/A	NDA Approval obtained
	Y-2 sublingual tablets (Y-2舌下片)	Small molecule drug	Free radicals and inflammatory cytokines	Acute ischemic stroke	Collaboration with YenePharma	Phase I clinical trials
	SIM-307	Small molecule drug	AQP4	Cerebral edema caused by stroke	Collaboration with Aeromics	Preparation for IND application
	SIM-339	Small molecule drug - peptide therapeutics	DAPK1	Cerebral infarction	Collaboration with Primary Peptides	Pre-clinical
Autoimmune	SIM-335	Small molecule drug	Multiple cytokines	Psoriasis	N/A	IND approval obtained
	Iguratimod tablets (New indication) (艾拉莫德片(新适应症))	Small molecule drug	Inflammatory cytokines and immunoglobulins	Sjögren's syndrome	N/A	IND application submitted
	SIM-295	Small molecule drug	URAT1	Gout with hyperuricemia	Collaboration with JW Pharmaceutical	Preparation for IND application

R&D partner has filed NDA for the indication of hemotherapy-induced myelosuppression in SCLC in U.S.

R&D partner has initiated phase I clinical trials in U.S

R&D partner has completed phase I clinical trials in U.S

R&D partner has initiated phase IIb clinical trials in U.S

Source: Company data, CMBIS

Well-established commercialization capabilities

The Company is a vertically integrated pharmaceutical company with established manufacturing and commercial capabilities. The Company maintains an effective and nationwide sales and distribution network supported by over 2,800 sales and marketing personnel spanning 31 provinces, municipalities and autonomous regions across China as of 30 Jun 2020, covering approximately 2,100 Class III hospitals, approximately 17,000 other hospitals and medical institutions, as well as more than 200 large-scale national or regional pharmacy chains.

The Company's leading commercial capabilities have enabled it to continuously procure its products' entry into the NRDL as well as clinical practice guidelines and pathways. As of 30 Jun 2020, the Company's existing product portfolio included over 30 products in the NRDL and over 10 products recommended in more than 40 clinical practice guidelines and pathways issued by government authorities or prestigious professional associations.

To supplement its in-house sales and marketing capabilities, the Company engages third-party promoters to promote its products in medical institutions located in lower-tier cities or regions or that are otherwise not covered by the Company's in-house sales and marketing team. The Company selects third-party promoters based on their qualifications, reputation, marketing experience, management capabilities and hospital coverage. As of 30 Jun 2020, the Company had 81 third-party promoters.

The Company currently has five GMP certified production facilities in China for the manufacturing of its pharmaceutical products, including one located in Nanjing, Jiangsu Province, two located in Hainan Province, one located in Yantai, Shandong Province and one located in Wuhu, Anhui Province. The Company's production facilities house a total of 21 production lines for the production of biologics and small molecule pharmaceuticals in a variety of dosage forms including injectables, oral liquids, oral solid dosage forms (tablets, capsules, granules and powders), implants, gel and dry powder for inhalation, as well as five workshops for the production of APIs. The Company has received EU GMP certification or passed the US FDA inspection for some of its production workshops. Moreover, The Company has a production facility for mAbs and other biologics in its pipeline, which is expected to commence pilot-scale production in December 2020. Furthermore, considering the complexity and difficulty in the manufacturing of cell therapy pharmaceuticals, the Company is currently constructing a new pilot-scale GMP-grade workshop for CMC and clinical research of the cell therapy pharmaceuticals in its product pipeline. The Company also plans to construct a new production facility for the commercial-scale production of cell therapy pharmaceuticals in its product pipeline in preparation for their commercial launch.

Diversified Product Portfolio

Oncology portfolio

The Company's oncology product portfolio currently comprises five products, including four major products: Endostar, Jepaso, Jiebaili and Sinofuan. In 2017, 2018, and 2019, sales of the oncology products were RMB1,004.9mn, RMB1,279.8mn, and RMB1,568.9mn, respectively, accounting for 26.2%, 29.7%, and 32.7% of revenue from sales of pharmaceutical products.

According to F&S, oncology was the 5th largest therapeutic area in China in terms of sales revenue of pharmaceuticals in 2019, accounting for 11.2% of the overall pharmaceutical market in the same year. In terms of sales revenue, the oncology pharmaceutical market grew at a CAGR of 13.5% from RMB110.2bn in 2015 to RMB182.7bn in 2019, and is expected to grow further at a CAGR of 15.4% from 2020 to 2024, reaching RMB367.2bn in 2024. The significant unmet clinical demands, increase in patients' affordability and willingness to pay for treatment, favourable government policies to support the development of innovative pharmaceuticals as well as combination therapies will continue to drive the rapid growth of the oncology pharmaceutical market in China, according to F&S.

Endostar (Recombinant Human Endostatin) 恩度 (重组人血管内皮抑制素)

Endostar (recombinant human endostatin injection), the Company's category I innovative biologic drug, is the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide, according to F&S. It is also the first innovative biologics approved for sale in China as first-line treatment for NSCLC. The Company held one invention patent on the compound of Endostar in the US, which was valid until 2023.

Recombinant human endostatin is a genetically engineered protein that inhibits the growth of blood vessels to a tumor, thereby slowing and preventing the growth and metastasis of tumor cells. Endostar is a targeted cancer therapy drug which, in combination with NP chemotherapy regimen, can be used to treat early and recurrent stage III/IV NSCLC.

The Company's phase III clinical trials, completed in 2004, demonstrated that, compared with NP chemotherapy regimen alone, combining Endostar with NP chemotherapy regimen can significantly extend advanced NSCLC patients' median time to progression (TTP) and overall survival (OS) and improve their quality of life. The Company commenced phase IV post-marketing clinical trials in 2006, enrolling an aggregate of 2,725 subjects. According to the phase IV clinical trials, combining Endostar with other different first-line chemotherapies, including NP regimen, gemcitabine/cisplatin (GP) regimen, paclitaxel/carboplatin (TC) regimen and docetaxel and cisplatin (DP) regimen, could all slow down disease progression in advanced NSCLC patients (median time to progression (TTP) of 7.6 months and median OS of 17.6 months) with a favourable safety profile. In addition, trial results did not demonstrate a significant difference in efficacy among the four groups of Endostar-combined chemotherapy.

Recombinant human endostatin is recommended by a number of oncology clinical practice guidelines in China as a first-line therapy for advanced NSCLC patients. In particular, it has been recommended by the "Primary Lung Cancer Diagnosis and Treatment Standards" (《原发性肺癌诊疗规范》) issued by NHC in 2015 and 2018, the "Clinical Pathways for NSCLC (2016)" (《非小细胞肺癌化疗临床路径(2016 版)》) issued by the NHC, the "Chinese Medical Association Guideline for Clinical Diagnosis and Treatment of Lung

Cancer (2018)" (《中华医学会肺癌临床诊疗指南(2018 版)》) issued by the Chinese Medical Association, the "Guidelines of Chinese Society of Clinical Oncology (CSCO) Primary Lung Cancer (2019)" (《中国临床肿瘤学会原发性肺癌诊疗指南(2019 版)》), and the "Chinese Expert Consensus on Anti-angiogenic Drugs for Advanced NSCLC (2019)" (《晚期非小细胞肺癌抗血管生成药物治疗中国专家共识(2019 版)》) issued by the CSCO. Moreover, recombinant human endostatin has been recommended as a first-line therapy for malignant melanoma and osteosarcoma by relevant clinical practice guidelines issued by the CSCO.

Endostar (recombinant human endostatin injection) was included in the NRDL in 2017 through the national medical insurance pricing negotiation process, which was successfully renewed in 2019. Sales of Endostar accounted for 17.3%, 19.0%, and 22.6% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Endostar increased from RMB669.7mn in 2017 to RMB1,136.5mn in 2019, representing a CAGR of 30.3%, while sales of Endostar decreased by 15.1% from RMB457.5mn for the six months ended 30 Jun 2019 to RMB388.6mn for the six months ended 30 Jun 2020.

In terms of sales revenue, the market for targeted therapy drugs for NSCLC in China grew at a CAGR of 40.8% from 2015 to 2019, reaching RMB20.8bn in 2019. Recombinant human endostatin was the seventh best-selling category of targeted therapy drug for NSCLC in terms of sales revenue in 2019, with a market share of 5.9%, according to F&S.

Jepaso (Nedaplatin) 捷佰舒 (奈达铂)

Jepaso (nedaplatin for injection), the Company's first-to-market generic pharmaceutical, is primarily used for the treatment of solid tumors such as head and neck neoplasms, small cell lung cancer, NSCLC, esophagus cancer and ovarian cancer. It is the first nedaplatin pharmaceutical product approved for sale in China, according to F&S. The originator product of Jepaso was developed by Shionogi and was launched in Japan in 1995.

After nedaplatin enters into a cell, it releases aglycone of glycolate and inhibits the replication of DNA and thereby prevents the growth of tumor cells. As a second-generation platinum-based drug, nedaplatin is more soluble in water and appears to be less toxic to kidney and the digestive system compared with cisplatin, the first-generation platinum-based drug, and therefore more suitable for elderly patients as well as patients with renal insufficiency. According to various independent clinical studies, nedaplatin does not have full cross resistance against other platinum-based chemotherapy drugs and can be the preferred platinum-based chemotherapy drug for the treatment of esophagus cancer and head and neck neoplasms. According to a 2015 independent clinical research, nedaplatin-based chemotherapy significantly prolongs overall survival in patients with squamous cell lung cancer and is likely to be the new-generation standard treatment for advanced or recurrent NSCLC.

Attributable to its effectiveness in the treatment of esophagus cancer and mild adverse reactions, nedaplatin has gained wide recognition among healthcare professionals in China, and has been listed as a recommended first-line chemotherapy or palliative chemotherapy for esophagus cancer in various clinical practice guidelines, including, among others, the "Clinical Pathways for Esophagus Cancer Chemotherapy (2016)" (《食管癌化疗临床路径(2016 版)》) issued by NHC, the "Standardized Esophagus Cancer Diagnosis and Treatment Guidelines (the Second Edition)" (《食管癌规范化诊疗指南(第二版)》)

published by China Union Medical University Press (中国协和医科大学出版社), and the "China Esophagus Cancer Radiotherapy Guidelines (2019)" (《中国食管癌放射治疗指南(2019 版)》) issued by CACA. Nedaplatin has also been recommended as a first-line therapy for advanced squamous cell lung cancer by the "Clinical Pathways for NSCLC Chemotherapy (2016)" (《非小细胞肺癌化疗临床路径(2016 版)》) issued by NHC and the "Primary Lung Cancer Diagnosis and Treatment Guidelines (2019)" (《原发性肺癌诊疗指南(2019 版)》) issued by CSCO. In addition, Jepaso has been included in the "Consensus among Experts on Metastatic Nasopharynx Cancer (2018)" (《转移性鼻咽癌专家共识(2018 版)》) issued by CACA as a treatment option for nasopharynx cancer.

Nedaplatin has been included in the NRDL since 2009. Sales of Jepaso accounted for 3.4%, 3.6%, and 3.4% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Jepaso increased from RMB132.9mn in 2017 to RMB173.1mn in 2019, representing a CAGR of 14.1%, while sales volume of Jepaso decreased by 16.2% from RMB79.0mn for the six months ended 30 Jun 2019 to RMB66.2mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the platinum-based drug market in China grew at a CAGR of 9.9% from 2015 to 2019, while the nedaplatin drug market in China, being its third largest segment, grew at a CAGR of 0.4% during the same period, reaching RMB558.2mn in 2019. The Company was the first largest manufacturer in the nedaplatin drug market in China in terms of sales revenue in 2019, with a market share of 33.7%, according to F&S.

Jiebaili (Pemetrexed Disodium) 捷佰立 (培美曲塞二钠)

Jiebaili (pemetrexed disodium for injection), the Company's generic drug, is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication and thereby prevents the growth of tumor cells. Jiebaili can be either used alone or in combination with other chemotherapy drugs and/or targeted drugs. The originator product of Jiebaili was developed by Eli Lilly and was launched in the US in 2004.

Pemetrexed disodium has been included in various clinical practice guidelines as a full-line therapy for non-squamous NSCLC and a first-line therapy for pleural mesothelioma, including, among others, the "Primary Lung Cancer Diagnosis and Treatment Guidelines (2019)" (《原发性肺癌诊疗指南(2019 版)》) and the "Consensus among Chinese Experts on Anti-angiogenic Drug for Treatment of Advanced NSCLC (2019)" (《晚期非小细胞肺癌抗血管生成药物治疗中国专家共识(2019 版)》) issued by CSCO, the "Clinical Practice Guidelines in Oncology – NSCLC (2019, the Fifth Version)" (《临床实践指南之非小细胞肺癌(2019 年第五版)》) and the "Clinical Practice Guidelines in Oncology – Malignant Pleural Mesothelioma (2019, the Second Version)" (《临床实践指南之恶性胸膜间皮瘤(2019 年第二版)》) issued by the National Comprehensive Cancer Network, a not-for-profit alliance of leading cancer centres in the US. Pemetrexed disodium has also been included in the "Clinical Practice Guidelines in Oncology – Cervical Cancer (2019, the Fourth Version)" (《临床实践指南之宫颈癌(2019 年第四版)》) issued by the National Comprehensive Cancer Network.

Pemetrexed has been included in the NRDL since 2017. Sales of Jiebaili accounted for 2.2%, 3.2%, and 2.5% of the Company's total revenue in 2017, 2018, and 2019,

respectively. The Company's revenue derived from sales of Jiebaili increased from RMB85.7mn in 2017 to RMB127.0mn in 2019, representing a CAGR of 21.7%. Sales of Jiebaili decreased by 73.8% from RMB70.1mn for the six months ended 30 Jun 2019 to RMB18.4mn for the six months ended 30 Jun 2020, which was due to i) the decrease in its sales volume as it was ineligible for bidding under the centralized volume-based drug procurement schemes; and ii) the decrease in its pricing level primarily attributable to downward pricing pressure brought by the centralized volume-based drug procurement schemes.

According to F&S, in terms of sales revenue, the pemetrexed drug market in China grew at a CAGR of 9.5% from 2015 to 2019, reaching RMB3.4bn in 2019. The Company was the sixth largest manufacturer in the pemetrexed drug market in China in terms of sales revenue in 2019, with a market share of 4.0%, according to F&S.

Sinofuan (5-Fluorouracil) 中人氟安 (5-氟尿嘧啶)

Sinofuan (5-fluorouracil implants), the Company's new formulation drug, is the only domestic antineoplastic sustained-release implant approved for sale in China, according to F&S. 5-Fluorouracil is primarily used for treatment of digestive system tumors, including esophagus cancer, colorectal cancer and gastric cancer. As a nucleoside metabolic inhibitor, 5-fluorouracil works by inhibiting the synthesis of DNA and RNA and thereby preventing the growth of tumor cells. Sustained-release implant, as a novel dosage form used in the treatment of digestive system tumors, significantly enhances the local concentration of 5-fluorouracil shortly after administration and provides constant release over an extended period, while minimizing systemic toxicity and side effects.

As a recommended intraoperative chemotherapy drug for colorectal cancer, 5-fluorouracil has been included in the "Consensus among Chinese Experts on Drugs Used in Abdominal Cavity for Prevention and Treatment of Peritoneal Metastasis of Colorectal Cancer (2019)" (《结直肠癌腹膜转移预防和治疗腹腔用药中国专家共识(2019 版)》) and the "Consensus among Experts on NOSES for Colorectal Neoplasm (2019)" (《结直肠肿瘤经自然腔道取标本手术专家共识(2019 版)》) issued by the Chinese Medical Doctor Association (中国医师协会). In addition, 5-fluorouracil has been included in the "Interpretation of Clinical Pathways Therapy Drugs – Oncology Disease Volume (2015)" (《临床路径治疗药物释义–肿瘤疾病分册(2015 年)》) published by China Union Medical University Press as a recommended intraoperative chemotherapy drug for gastric cancer, colorectal cancer and liver cancer.

Sales of Sinofuan accounted for 3.0%, 2.6%, and 2.5% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Sinofuan increased from RMB116.6mn in 2017 to RMB128.3mn in 2019, while sales of Sinofuan increased by 6.0% from RMB54.3mn for the six months ended 30 Jun 2019 to RMB57.5mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the intraoperative chemotherapy drug for digestive system cancer market in China grew at a CAGR of 29.9% from 2015 to 2019, reaching RMB2.1bn in 2019. Sinofuan accounted for 6.6% of the intraoperative chemotherapy drug for digestive system cancer market in China in terms of sales revenue in 2019, according to F&S.

Central nervous system portfolio

The Company's central nervous system product portfolio currently comprises three products, including one of its major products, Bicun. In 2017, 2018, and 2019, the Company's sales of central nervous system products were RMB1,276.1mn, RMB1,202.0mn, and RMB936.9mn, respectively, accounting for 33.3%, 27.9%, and 19.5% of revenue from sales of pharmaceutical products.

According to F&S, central nervous system diseases were the 4th largest therapeutic area in China in terms of sales revenue of pharmaceuticals in 2019, accounting for 12.5% of the overall pharmaceutical market in the same year. In terms of sales revenue, the central nervous system pharmaceutical market in China grew at a CAGR of 9.1% from RMB144.0bn in 2015 to RMB204.3bn in 2019. The central nervous system pharmaceutical market in China is expected to grow further at a CAGR of 4.6% from 2020 to 2024, reaching RMB250.9bn in 2024. The central nervous system pharmaceutical market in China is expected to continue its growth leveraging key drivers including an increasing number of patients as well as their increasing disposable income, launch of new products and indication expansion of existing products, according to F&S.

Bicun (Edaravone) 必存 (依达拉奉)

Bicun (edaravone injection), the Company's first-to-market generic pharmaceutical for the treatment of acute cerebral infarction, is the first edaravone injection approved for sale in China and the second edaravone injection approved for sale worldwide, according to F&S. The originator product of Bicun was developed by Mitsubishi Tanabe Pharma Corporation and was launched in Japan in 2001.

Edaravone is a synthetic free radical scavenger used to improve the neurological symptoms and dysfunction of activities of daily living caused by acute cerebral infarction. Edaravone protects the brain by eliminating excessive free radicals, which are highly reactive molecules occurring in the human body as a result of cerebral infarction that could result in damage to cerebral cells. Meanwhile, it inhibits the decrease of regional cerebral blood flow in cerebral infarction. Edaravone is a neuroprotective agent that has been proven as effective and safe in improving the functional outcomes of patients with acute cerebral infarction, according to multiple randomized, double-blind placebo controlled clinical trials both in China and abroad.

Edaravone has been recommended by a number of clinical practice guidelines and consensus in China and abroad for treatment of stroke, such as the "Acute Ischemic Stroke Diagnosis and Treatment Guidelines" (《中国急性缺血性脑卒中诊治指南》) issued by Chinese Medical Association in 2010, 2015 and 2018, the "Guidelines for the Early Management of Patients with Acute Ischemic Stroke" issued by American Heart Association and American Stroke Association in 2007 and 2013, the "Cerebral Hemorrhage Diagnosis and Treatment Guidelines" (《脑出血诊治指南》) issued by Chinese Medical Association in 2015, the "Clinical Pathways for Cerebral Infarction (2016)" (《脑梗死临床路径(2016版)》), the "Clinical Pathways for Cerebral Hemorrhage (2016)" (《脑出血临床路径(2016版)》) and the "Acute-Stage Ischemic Stroke Diagnosis and Treatment Guidelines (2017)" (《缺血性脑卒中急性期诊疗指导规范(2017版)》) issued by the NHC, the "Japanese Guidelines for the Management of Stroke 2015 (2017 Revised)" issued by the Japan Stroke Society, and the "China Cerebrovascular Disease Clinical Management

Guidelines (2019)" (《中国脑血管病临床管理指南(2019 版)》) issued by the China Stroke Association.

Sales of Bicun accounted for 32.2%, 26.6%, and 18.6% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Bicun was RMB1,244.2mn, RMB1,198.6mn, and RMB936.9mn in 2017, 2018, and 2019, respectively, while sales of Bicun decreased by 68.9% from RMB572.8mn for the six months ended 30 Jun 2019 to RMB178.0mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue in 2019, the size of the edaravone drug market in China, being the third largest segment of the neuroprotective agent market in China, amounted to RMB2.9bn. Bicun was the best-selling edaravone drug in terms of sales revenue in 2019, with a market share of 36.8%, according to F&S.

Autoimmune portfolio

The Company's autoimmune product portfolio currently comprises five products, including the Company's core autoimmune product, Iremod (iguratimod tablets). In 2017, 2018, and 2019, the Company's sales of autoimmune products were RMB423.2mn, RMB537.8mn, and RMB813.8mn, respectively, accounting for 11.0%, 12.5%, and 17.0% of revenue from sales of pharmaceutical products.

According to F&S, autoimmune diseases were one of the fastest growing therapeutic areas in China in terms of sales revenue of pharmaceuticals in 2019. In terms of sales revenue, the autoimmune pharmaceutical market grew at a CAGR of 13.4% from RMB9.8bn in 2015 to RMB16.2bn in 2019, and is expected to grow further at a CAGR of 27.2% from 2020 to 2024, reaching RMB53.2bn in 2024. An increasing number of patients, as well as their increasing disposable income and health awareness, the inclusion of additional pharmaceuticals into the NRDL, the improvement of diagnosis and treatment level, and the development of innovative therapies and pharmaceuticals are expected to continue to drive the future growth of the autoimmune pharmaceutical market in China, according to F&S.

Iremod (Iguratimod) 艾得辛 (艾拉莫德)

Iremod (iguratimod tablets), the Company's category I innovative chemical drug for the treatment of active rheumatoid arthritis, is the only iguratimod pharmaceutical product approved for sale in China and the first iguratimod pharmaceutical product approved for sale in the world, according to F&S.

Iguratimod is a type of conventional synthetic DMARD that slows down the progression of active rheumatoid arthritis by inhibiting the generation of inflammatory cytokines. According to the Company's phase III clinical trials that commenced in 2008, Iremod administered as a monotherapy in rheumatoid arthritis patients has shown ACR20 (meaning at least a 20% improvement in rheumatoid arthritis symptoms) response rate of 63.8% at week 24. According to a randomized, double-blind, parallel-controlled clinical trial conducted in Japan in 2013, iguratimod administered in combination with other drugs in rheumatoid arthritis patients has shown an ACR20 response rate of 71.3% at week 52. According to the Company's phase IV post-marketing clinical trials that commenced in 2012, Iremod administered in combination with other drugs in rheumatoid arthritis patients has demonstrated an ACR20 response rate of 71.9% at week 24. As an orally-administered chemical drug, Iremod is easier to administer and more affordable than biologic DMARDs

that are costly and require intravenous or subcutaneous injections, offering the potential to significantly improve the symptoms of active rheumatoid arthritis patients.

Iguratimod has been recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinical practice guidelines. In particular, it has been recommended by the "Guidelines for the Diagnosis and Treatment of Rheumatoid Arthritis" issued by the Ministry of Health, Labor and Welfare of Japan in 2014, the "Rheumatoid Arthritis Treatment Guidelines" (《类风湿关节炎治疗指南》) issued by the Asia Pacific League of Associations for Rheumatology in 2015 and 2018, the "Clinical Pathways for Rheumatoid Arthritis" (《类风湿性关节炎临床路径》) issued by the NHC in 2016, and the "China Rheumatoid Arthritis Diagnosis and Treatment Guidelines" (《中国类风湿关节炎诊疗指南》) issued by the Chinese Medical Association in 2018.

Iguratimod has been included in the NRDL since 2017. Sales of Iremod accounted for 4.1%, 6.5%, and 10.3% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Iremod increased from RMB159.0mn in 2017 to RMB520.2mn in 2019, representing a CAGR of 80.9%, while sales volume of Iremod increased from approximately 14.7mn tablets in 2017 to approximately 47.7mn tablets in 2019, representing a CAGR of 79.9%. Revenue of Iremod increased by 91.1% from RMB203.8mn for the six months ended 30 Jun 2019 to RMB389.5mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the conventional synthetic DMARD market in China grew at a CAGR of 12.4% from 2015 to 2019, reaching RMB3.1bn in 2019. Iguratimod was the third best-selling conventional synthetic DMARD in terms of sales revenue in 2019, with a market share of 18.4%, according to F&S.

Yingtaiqing (Diclofenac Sodium) 英太青 (双氯芬酸钠)

Yingtaiqing (diclofenac sodium sustained-release capsules and gel) is a non-steroidal anti-inflammatory analgesic drug for the treatment and relief of pain caused by rheumatoid arthritis and osteoarthritis, soft tissue rheumatic pains and various mild and moderate body aches. It eases pain and reduces inflammation by blocking the effect of cyclooxygenase enzymes, which produce prostaglandins in the body that cause pain and inflammation. With its unique sustained-release pellet technology, it becomes effective within one hour and lasts up to 12 hours, providing fast and effective pain relief.

Non-steroidal anti-inflammatory drugs have been recommended as the primary therapy for osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in the "Osteoarthritis Diagnosis and Treatment Guidelines" (《骨关节炎诊疗指南》) issued by Chinese Medical Association in 2018, and the "Clinical Pathways for Osteoarthritis" (《骨关节炎临床路径》), the "Clinical Pathways for Rheumatoid Arthritis" (《类风湿性关节炎临床路径》), and the "Clinical Pathways for Ankylosing Spondylitis" (《强直性脊柱炎临床路径》) issued by the NHC in 2016.

The Company currently sells and/or promotes Yingtaiqing-branded sustained-release capsules and gel in China. During the Track Record Period, a substantial portion of the Yingtaiqing-branded sustained-release capsules that the Company sold and/or promoted were produced by a third-party manufacturer, CPU Pharma, pursuant to exclusive agreements with CPU Pharma. The Company has also obtained the NMPA approval to produce and sell diclofenac sodium sustained-release capsules and gel in 2002 and 2005, respectively.

Diclofenac sodium sustained-release capsules have been included in the NRDL since 2004. Sales of Yingtaiqing accounted for 6.8%, 5.4%, and 5.8% of the Company's total revenue in 2017, 2018, and 2019, respectively, of which sales of Yingtaiqing-branded capsules contributed to a substantial portion. The Company's revenue derived from sales of Yingtaiqing increased from RMB261.5mn in 2017 to RMB289.9mn in 2019, representing a CAGR of 5.3%. The Company's sales of Yingtaiqing increased by 18.2% from RMB123.7mn for the six months ended 30 Jun 2019 to RMB146.2mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the non-steroidal anti-inflammatory drug market in China grew at a CAGR of 13.6% from 2015 to 2019, while the mono-ingredient diclofenac sodium drug market in China grew at a CAGR of 11.0% during the same period, reaching RMB1.7bn in 2019. The Company ranked the first in mono-ingredient diclofenac sodium drug market in China in terms of sales revenue in 2019, with a market share of 18.1%, according to F&S.

Orencia (abatacept injection) 恩瑞舒 (阿巴西普注射液)

Simcere has been collaborating with BMS on the development and commercialization of abatacept injection in China. The Company has launched the drug in China in Aug 2020.

Abatacept injection is for the treatment of moderate to severe rheumatoid arthritis. Abatacept injection is the first and only soluble CTLA4-Fc fusion protein approved for sale in China and the first and only selective T-cell co-stimulation modulator in the autoimmune disease therapeutic area worldwide, according to F&S. It prevents the activation of T cells by binding to the natural ligands CD80 and CD86 on antigen-presenting cells, thereby blocking their interaction with CD28 on the T cells, and consequently reduces inflammation.

It may be used in combination with other DMARDs other than TNF-α inhibitors, such as methotrexate, to treat moderate to severe active rheumatoid arthritis patients who do not respond favorably to other DMARDs. Abatacept injection was developed by BMS and first approved for sale in the US in 2005 under the Orencia brand. It has also been launched in Europe and Japan with global sales of US$3.2bn in 2019, according to F&S. Simcere launched Orencia (abatacept injection) in China in Aug 2020.

According to a US claims database, the risk of hospitalized infection of patients who use abatacept injection was 22.6% lower than the commonly used TNF- α inhibitors. According to a head-to-head comparison study in 2014, abatacept injection, when using in combination with methotrexate, indicates similar efficacy and higher safety profile compared with adalimumab, a TNF- α inhibitor, when using in combination with methotrexate for treatment of rheumatoid arthritis patients. In June 2019, BMS announced data from a Phase IV mechanistic study exploring the differences between abatacept and adalimumab in interfering with disease progression in early moderate to severe rheumatoid arthritis patients seropositive for HLA-DRB1 shared epitope alleles. Trial results have shown higher efficacy responses from patients treated with abatacept.

Figure 6: Marketed biologics (other than abatacept injection) for RA in China (by 30 Jun 2020)

Generic name	Representative Product		Number of Other Manufacturers of Products with the Same Generic Name	Earliest Year of NMPA Approval	NRDL
	Brand name	Manufacturer			
Infliximab	Remicade	Janssen	0	2006	Part B
Adalimumab	Humira	Abbivie	2	2010	Part B
Etanercept	Enbrel	Pfizer	0	2010	Part B
Recombinant Human TNF-α Receptor II-IgG Fc Fusion Protein	Yisaipu	CP Guojian Pharmaceutical	2	2005	Part B
Golimumab	Simponi	Jassen	0	2017	Part B
Certolizumab Pegol	Cimzia	UCB	0	2018	No
Tocilizumab	Actemra	Roche	0	2013	Part B

Source: F&S analysis, CMBIS

Cardiovascular portfolio

The Company's cardiovascular product portfolio currently comprises three products, including one of its major products, Softan. The Company also markets and/or sells OLMETEC PLUS (Olmesartan medoxomil and hydrochlorothiazide tablets) developed and manufactured by Daiichi Sankyo. Angiotensin II receptor blocker is the most prescribed category of anti-hypertensive pharmaceuticals worldwide according to F&S, while OLMETEC PLUS is a new-generation fixed-dose combination of an angiotensin II receptor blocker, olmesartan medoxomil, and a thiazide diuretic, hydrochlorothiazide, and an exclusive product in China pharmaceutical market.

In 2017, 2018, and 2019, the Company's sales of cardiovascular products were RMB243.4mn, RMB353.1mn, and RMB445.5mn, respectively, accounting for 6.3%, 8.2%, and 9.3% of revenue from sales of pharmaceutical products, respectively.

According to F&S, sales revenue of cardiovascular pharmaceuticals accounted for 13.0% of the overall pharmaceutical market in 2019. In terms of sales revenue, the cardiovascular pharmaceutical market in China grew at a CAGR of 7.5% from RMB158.8bn in 2015 to RMB212.2bn in 2019, and is expected to grow further at a CAGR of 3.3% from RMB217.5bn in 2020 to RMB247.7bn in 2024.

Softan (Rosuvastatin Calcium) 舒夫坦 (瑞舒伐他汀钙)

Softan (rosuvastatin calcium tablets), the Company's generic pharmaceutical, is a selective inhibitor of HMG-CoA reductase and a cholesterol lowering statin. Softan lowers the cholesterol level by increasing the number of receptors on liver cells to augment the uptake and catabolism of LDL while inhibiting the synthesis of VLDL in the liver, and thereby reducing both LDL and VLDL levels. Moreover, it can be used by patients to reduce the risk of cardiovascular diseases or the need for medical procedures to open blocked heart vessels.

It is used to treat patients with primary hypercholesterolemia (type IIa) or mixed dyslipidemia (type IIb) whose blood cholesterol levels cannot be properly controlled through dieting or other non-medication therapies. It can also be used as an adjunctive therapy for patients with homozygous familial hypercholesterolemia. The statin therapies for elevated lipid levels compared across doses to rosuvastatin trial shows that rosuvastatin is more effective in lowering low-density cholesterol than other commonly used statins. The originator product of Softan was developed by AstraZeneca and was launched in China in 2004.

Rosuvastatin calcium has been included in a number of clinical practice guidelines in China as a recommended therapy drug for dyslipidemia, including the "China Adults Dyslipidemia Prevention and Treatment Guidelines (2016 Revised)" (《中国成人血脂异常防治指南(2016 修订版)》) issued by a joint commission of multi-disciplinary experts and the "Guidelines for Rational Drug Use for Dyslipidemia (2019)" (《血脂异常合理用药指南(2019 版)》) issued by the NHC. Meanwhile, it has been recommended by various clinical practice guidelines in the US, Canada and the European Union as the first-line treatment for lowering blood cholesterol, such as the "Canadian Guidelines for the Diagnosis and Treatment of Dyslipidemia and Prevention of Cardiovascular Disease in the Adult" issued by Canadian Cardiovascular Society in 2009, and the "Guidelines on the Management of Blood Cholesterol" issued by the American College of Cardiology and the American Heart Association in 2013 and 2018.

Rosuvastatin has been included in the NRDL since 2009. Sales of Softan accounted for 4.6%, 6.2%, and 6.6% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Softan increased from RMB179.2mn in 2017 to RMB334.9mnin 2019, representing a CAGR of 36.7%, while sales volume of Softan increased from approximately 77.8mn tablets in 2017 to approximately 176.9mn tablets in 2019, representing a CAGR of 50.8%, according to F&S. Sales of Softan decreased by 27.1% from RMB166.9mn for the six months ended 30 Jun 2019 to RMB 121.6mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the rosuvastatin market in China grew at a CAGR of 12.7% from 2015 to 2019, reaching RMB6.8bn in 2019. The Company was the fifth largest player in the rosuvastatin drug market in China in terms of sales revenue in 2019, with a market share of 5.4%.

Anti-infective portfolio

The Company's anti-infective product portfolio currently comprises 16 products, including two of its major products, Newanti and ZAILIN. Its anti-infective product portfolio also includes the ZAILIKE-branded arbidol dispersible tablets, broad-spectrum anti-viral for treatment of influenza. Arbidol has been included in the NRDL in 2019. Arbidol is a hemagglutinin fusion inhibitor and was proven to be effective against viruses resistant to oseltamivir, a neuraminidase inhibitor. Arbidol is recommended by the NHC in its "Guidelines for the Diagnosis and Treatment of Influenza (2019 Edition)" (《流行性感冒诊疗方案(2019 年版)》) and "Guidelines for the Diagnosis and Treatment of COVID-19 (Sixth/Seventh Editions for Trial Implementation)" (《新冠肺炎诊疗方案(试行第六版、第七版)》).

In 2017, 2018, and 2019, the Company's sales of anti-infective products were RMB564.7mn, RMB579.5mn, and RMB635.7mn, respectively, accounting for 14.7%, 13.4%, and 13.2% of revenue from sales of pharmaceutical products.

According to F&S, sales revenue of anti-infective pharmaceuticals accounted for 13.8% of the overall pharmaceutical market in 2019. In terms of sales revenue, the anti-infective market in China grew at a CAGR of 3.6% from RMB195.8bn in 2015 to RMB225.5bn in 2019, and is expected to grow further at a CAGR of 3.2% from RMB230.0bn in 2020 to RMB260.7bn in 2024.

Newanti (Biapenem) 安信 (比阿培南)

Newanti (biapenem for injection), the Company's first-to-market generic pharmaceutical, is a new-generation carbapenem antibiotic for injection and the first biapenem pharmaceutical product approved for sale in China, according to F&S. Newanti is used for the treatment of moderate to severe bacterial infections, such as septicemia, pneumonia and lung abscess caused by sensitive bacteria, secondary infections caused by chronic respiratory disease, refractory cystitis, pyelonephritis, peritonitis and annexitis. It is primarily used to treat critically-ill, hospitalized patients suffering from serious infections, and is predominantly consumed in hospitals' intensive care units and respiratory and hematology departments.

According to a 2012 clinical research jointly conducted by the Guangzhou Institute of Respiratory Diseases (广州呼吸疾病研究所) and the Company, Newanti has stronger in-vitro antibacterial activity for multiple strains of common bacteria, compared to meropenem and imipenem, its competing products. According to independent clinical trial reports issued in 2012, biapenem is more effective in treating moderate to severe lower respiratory infection with lower incidence of adverse events in central nervous system, as compared to imipenem/cilastatin. According to independent clinical trial reports issued in 2016, biapenem indicates similar efficacy and safety profile in treating lower respiratory infection, complicated urinary tract infection and complex intra-abdominal infection, as compared to meropenem and imipenem/cilastatin. The originator product of Newanti was developed by Meiji Seika and was launched in Japan in 2001.

Biapenem has been recommended as a primary carbapenem antibiotic in a number of clinical practice guidelines, including the "National Guidelines for Antimicrobial Therapy" (《国家抗微生物治疗指南》) issued by NHC in 2012, the "Guidelines for Clinical Application of Antibacterial Drugs (2015)" (《抗菌药物临床应用指导原则 2015 年版》) issued by NHC, the "China Adults Community-Acquired Pneumonia Diagnosis and Treatment Guidelines (2016)" (《中国成人小区获得性肺炎诊断和治疗指南(2016 版)》) and the "China Adults Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia Diagnosis and Treatment Guidelines (2018)" (《中国成人医院获得性肺炎与呼吸机相关性肺炎诊断和治疗指南(2018 版)》), and the "Consensus among Experts on Diagnosis and Treatment for End-Stage Liver Disease with Infection (2018)" (《终末期肝病合并感染诊治专家共识(2018 版)》) issued by Chinese Medical Association. Moreover, biapenem has also been recommended by the "Guidelines for Treatment of Respiratory Tract Infection" issued by the Japanese Association for Infectious Diseases and Japanese Society of Chemotherapy in Japan in 2016.

Biapenem has been included in the NRDL since 2009. Sales of Newanti accounted for 6.6%, 5.7%, and 5.6% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of Newanti increased from RMB257.1mn in 2017 to RMB283.9mn in 2019, representing a CAGR of 5.1%, while sales volume of Newanti increased from approximately 2.4mn vials in 2017 to approximately 3.2mn vials in 2019, representing a CAGR of 15.9%. Sales of Newanti decreased by 27.0% from RMB136.9mn for the six months ended 30 Jun 2019 to RMB99.9mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the carbapenem drug market in China grew at a CAGR of 6.6% from 2015 to 2019 in terms of sales revenue, while the biapenem drug market in China, being its third largest segment, grew at a CAGR of 2.1% during the same

period, reaching RMB1.0bn in 2019. Newanti ranked second in the biapenem drug market in China in terms of sales revenue in 2019, with a market share of 32.5%, according to F&S.

ZAILIN (Amoxicillin) 再林 (阿莫西林)

ZAILIN is the brand name for the Company's line of generic amoxicillin antibiotics in dosage forms including capsules, dispersible tablets and granules. Amoxicillin is a type of semi-synthetic penicillin β-lactam antibiotic used for the treatment of various bacterial infections, such as upper respiratory infection of tympanitis, nasosinusitis, pharyngitis and amygdalitis, lower respiratory infection of acute bronchitis and pneumonia, urogenital infections and skin/soft tissue infections. Amoxicillin has been widely recommended in almost all the major clinical practice guidelines on the use of antibiotics.

Amoxicillin has been included in the NRDL since 2004. Sales of ZAILIN accounted for 4.9%, 4.2%, and 4.0% of the Company's total revenue in 2017, 2018, and 2019, respectively. The Company's revenue derived from sales of ZAILIN increased from RMB189.2mn in 2017 to RMB199.7mn in 2019, representing a CAGR of 2.7%. Sales volume of ZAILIN-branded capsules increased from approximately 200.4mn pills in 2017 to approximately 220.0mn in 2019, representing a CAGR of 4.8%; sales volume of ZAILIN-branded granules decreased slightly from approximately 306.1mn packs in 2017 to approximately 302.4mn packs in 2019; and sales volume of ZAILIN-branded tablets increased from approximately 64.4mn pills in 2017 to approximately 67.4mn pills in 2019, representing a CAGR of 2.4%. Sales of ZAILIN decreased by 41.9% from RMB93.9mn for the six months ended 30 Jun 2019 to RMB54.6mn for the six months ended 30 Jun 2020.

According to F&S, in terms of sales revenue, the mono-ingredient amoxicillin drug market in China grew at a CAGR of 1.2% from 2015 to 2019, reaching RMB3.0bn in 2019. The Company was the fourth largest manufacturer in the mono-ingredient amoxicillin drug market in China in terms of sales revenue in 2019, with a market share of 7.1%, according to F&S.

Rich innovative drug pipeline

Enhancing innovative drug R&D platforms

The Company's research and development activities are primarily conducted through three R&D centres in China, one in Shanghai, which primarily focuses on innovative pharmaceuticals; one in Nanjing, Jiangsu Province, which primarily focuses on innovative and high entry-barrier generic pharmaceuticals; and one in Boston, the US, which focuses on innovative and advanced therapies, particularly cell therapy.

The Company's R&D team comprises experts with extensive experience in drug discovery, pre-clinical development, pilot scale production, clinical development, and drug registration regulatory affairs, covering the entire R&D cycle. The Company primarily relies on its R&D team for the development of drug candidates, ultimately bringing them to market in a timely and cost-effective manner. As of 30 Jun 2020, the Company's R&D department consisted of 756 full-time employees, 331 of whom held master's degrees and 116 held Ph.D. degrees, featuring project leaders for NHFPC's "Major New Drug Creation" Science and Technology Major Projects (「重大新药创制」科技重大专项). Over 10% of the Company's employees in R&D department are scientists or former R&D personnel from overseas well-known pharmaceutical companies or universities.

The Company's R&D team maintains close interaction with its production and sales and marketing teams to advance the research and development projects in an efficient manner. For example, the Company's production and sales and marketing teams participate early in the research and development process, which enables the Company to reduce the risk of unanticipated technological obstacles in the manufacturing stage and focus on projects with attractive market potential. In addition, the Company's R&D team assists the production team in resolving technical issues and improving manufacturing processes and techniques.

As an innovation-driven pharmaceutical company, the Company was approved by the Ministry of Science and Technology of China in October 2015 to establish the only national key laboratory of translational medicine and innovative pharmaceuticals (转化医学与创新药物国家重点实验室) in China pharmaceutical industry. This laboratory focuses on the translational medicine and precision medicine-based research and development of innovative pharmaceuticals for the treatment of oncology, central nervous system diseases, autoimmune diseases, and infectious diseases.

In 2017, 2018, and 2019, the Company's research and development expenses were RMB212.3mn, RMB447.1mn, and RMB716.4mn, representing 5.5%, 9.9%, and 14.2% of the Company's total revenue, respectively. The Company's research and development capabilities have been recognized by various levels of the Chinese government.

Collaborating with partners to expand innovative drug pipelines

As an essential component of research and development model, the Company has entered into long-term collaboration arrangements with leading domestic and international pharmaceutical companies and biotechnology companies to in-license or co-develop innovative and high end generic drug candidates that have high potential for commercialization in China. These strategic partnerships further broaden the Company's access to competitive drug candidates, while minimizing costs and risks associated with their early-stage research and development. Its in-house R&D capabilities, proven track record of successful development, and commercialization of innovative pharmaceuticals, combined with established manufacturing and commercial capabilities, have made the Company an attractive partner of choice for domestic and international pharmaceutical companies and biotechnology companies seeking to unlock the value of their assets in the rapidly growing China pharmaceutical market. In addition, the Company engages in joint R&D collaborations with universities and other research institutions.

The Company's external R&D partners include (i) leading domestic and multinational pharmaceutical companies such as BMS and Amgen; (ii) dynamic domestic and international biotechnology companies such as Apexigen, Aeromics, Merus, JW Pharmaceutical, GI Innovation, Primary Peptides, GI Therapeutics, Jiangsu Alphamab, 3D Medicines Beijing, Immunochina, TCRCure Beijing, PREGENE, and YenePharma; and (iii) leading domestic and international universities and other research institutions such as Shanghai Jiao Tong University and Nanjing Medical University.

The Company's business development force is strategically located in the Nanjing headquarters, the US, and Great Britain, and they actively seek potential domestic and overseas collaboration opportunities. As of 30 Jun 2020, the Company's business development team consisted of 20 employees, who possessed an average of eight years of industry-related experience.

Figure 7: Simcere's major collaboration partners

Source: Company data, CMBIS estimates

Central nervous system product candidates

Edaravone and dexborneol concentrated solution for injection (依达拉奉右莰醇注射用浓溶液)

Edaravone and dexborneol concentrated solution for injection (brand name Sanbexin) is an innovative chemical drug candidate which the Company has been developing in-house. It is a compound of edaravone and dexborneol with a proven ratio of 4:1. Edaravone is an antioxidant and a free radical scavenger which scavenges hydroxyl free radical (OH), nitric oxide free radicals (NO) and peroxynitrite anion (ONOO−); while dexborneol is a bicyclic monoterpene which could inhibit the production or expression of pro-inflammatory cytokines such as TNF- α and interleukin-1 β as well as inflammation-related proteins such as cyclo-oxygenase-2 and induced nitric oxide synthase. With its dual mechanism of action, edaravone and dexborneol concentrated solution for injection scavenges free radicals, inhibits inflammatory response and improves the permeability in blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke.

A randomized, double-blind, positive controlled, head to head comparison phase III study in approximately 1,200 acute ischemic stroke patients has shown that, compared to edaravone monotherapy, edaravone and dexborneol concentrated solution for injection has significantly higher efficacy with similar safety profile, extending the therapeutic time window from 24 hours to 48 hours.

The Company has obtained the NDA approval from NMPA for the drug in July 2020. To date, the Company's edaravone and dexborneol concentrated solution for injection is the only edaravone and dexborneol concentrated solution for injection that had received approval for sale in the past five years worldwide. Recently, Sanbexin was added into the NRDL, effective from Mar 2021. Hence, we expect strong sales ramp-up for Sanbexin in coming years.

Y-2 sublingual tablets (Y-2 舌下片)

Y-2 sublingual tablets are the solid dosage form of edaravone dexborneol compound. Sequential therapy consisting of Y-2 sublingual tablets and edaravone and dexborneol concentrated solution for injection is designed to enable patients to receive a timely and complete treatment. In addition, administration of sublingual tablets is less dependent on medical conditions or compliance of patients, which makes it more suitable for research on new indications such as other chronic central nervous system diseases. Further, sublingual tablets have higher commercial value due to its lower production and transportation costs and larger patient base. The Company is currently conducting phase I clinical trials for Y-2 sublingual tablets in China and expects such clinical trials to be completed in the second half of 2020. The Company plans to initiate phase II clinical trials in China in 2021.

The Company is collaborating with YenePharma and its affiliates on the development and commercialization of this product candidate. YenePharma has initiated phase I clinical trials for Y-2 sublingual tablets in the US.

The Company entered into a collaboration agreement with YenePharma and certain of its affiliates on 28 Sep 2019 (the "YenePharma Collaboration Agreement"), pursuant to which the Company and YenePharma agreed to co-develop an edaravone compound in sublingual tablet dosage form, namely, Y-2 sublingual tablets. Upon receiving the necessary regulatory approvals, Simcere will have the exclusive right to manufacture, sell, license and otherwise commercialize the Y-2 sublingual tablets in the Greater China.

SIM-307

SIM-307 is a first-in-class compound developed based on the Nobel-prize winning water channel discovery. SIM-307 is a potent inhibitor of aquaporin-4 (AQP4) water channels intended for treatment of cerebral edema caused by acute ischemic stroke through intravenous infusion administration. Studies have demonstrated SIM-307 as an AQP4 inhibitor to be effective in control of cerebral edema. The Company is currently preparing for IND application for this product candidate and expects to initiate phase I clinical trials in China in 2021.

According to F&S, the incidence of clinically significant cerebral edema in China grew from 551.3 thousand in 2015 to 677.5 thousand in 2019, and is expected to grow further at a CAGR of 3.1% from 2020 to 2024, reaching 793.4 thousand in 2024. As of 30 Jun 2020, there was no AQP4 inhibitor approved for sale worldwide, and no AQP4 inhibitor candidate was at clinical stage in China.

The Company is collaborating with Aeromics on the development and commercialization of this product candidate. Aeromics has completed phase I clinical trial for SIM-307 in the US.

The Company entered into a license agreement with Aeromics in October 2019 (the "Aeromics License Agreement"), pursuant to which the Company was granted an exclusive and sub-licensable license to research, develop, manufacture, and commercialize an AQP4 inhibitor, namely, SIM-307, in the Greater China.

Oncology product candidates

KN035 (Envafolimab)

The Company entered into a tripartite collaboration agreement with Jiangsu Alphamab and 3D Medicines Beijing, together with a separate marketing and promotion agreement with 3D Medicines Beijing, on 30 Mar 2020, in respect of KN035 (collectively, the "KN035 Collaboration Agreements").

The KN035 Collaboration Agreements provide the Company with an exclusive promotion right in respect of oncology treatment indications of KN035 in mainland China. Pursuant to the KN035 Collaboration Agreements, Jiangsu Alphamab will manufacture, and 3D Medicines will sell, KN035 to the Company's designated distributors, while the Company is entitled to receive promotion service fees on a monthly basis calculated with reference to the total purchases made by its distributors and based on rates stipulated in the Collaboration Agreements. Pursuant to the KN035 Collaboration Agreements, the Company is entitled to make final decisions in respect of general matters including the commercialization of KN035 in mainland China, while reserved matters such as the pricing of KN035 shall be agreed upon unanimously by all three parties.

KN035 is potentially the first subcutaneously injectable anti-PD-L1 monoclonal antibody worldwide. The Company's collaboration partners are currently conducting phase II clinical trials of KN035 for dMMR/MSI-H colorectal carcinoma and other advanced solid tumors and phase III clinical trials for advanced BTC in mainland China as well as phase I clinical trials in the US and Japan. KN035 has submitted NDA to the NMPA for treatment of MSI-H solid tumors in Dec 2020 and is expected to be launched in the PRC market in 2021E.

As a subcutaneously injectable anti-PD-L1 monoclonal antibody, the Companies believes that KN035 may reach a broader patient group and could be a more valuable option for patients with advanced solid tumors who are not suitable for intravenous infusion. With its unique molecule design and approximately half of the clinical dosage of other anti-PD-L1

monoclonal antibodies launched in the market, KN035 has shown similar efficacy and safety profile. In particular, according to the clinical data released at the 2020 annual meeting of the American Society of Clinical Oncology, KN035 has demonstrated an ORR of 34.0% for dMMR/MSI-H advanced solid tumors and an ORR of 54.2% in the colorectal cancer patients who had prior therapy with fluoropyrimidine and oxaliplatin or irinotecan. In combination with FOLFOX, as a first-line therapy for advanced gastric cancer and gastroesophageal borderline tumor, the ORR is 60% and the median PFS is 6.8 months.

In addition to dMMR/MSI-H solid tumors and BTC, Jiangsu Alphamab and 3D Medicines are currently exploring opportunities to extend the indications of KN035 to other tumors. The Company plans to collaborate with Jiangsu Alphamab and 3D Medicines to develop a number of combination therapies with KN035 for the treatment of solid tumors, in order to further enhance the competitiveness of KN035.

According to F&S, the sales revenue of the PD-1/PD-L1 mAb market in China is expected to grow rapidly at a CAGR of 56.1% from RMB13.8bn in 2020 to RMB81.9bn in 2024. The Company expects KN035 has vast market potential and its launch will continue to allow the Company to capture market share in the oncology pharmaceutical market in China.

Sevacizumab (Humanized anti-VEGF monoclonal antibody for injection) (赛伐珠单抗，注射用人源化抗 VEGF 单克隆抗体)

Sevacizumab is a new-generation recombinant humanized anti-VEGF monoclonal antibody intended for the treatment of ovarian cancer. This product candidate targets the pro-angiogenic function of VEGF and thereby inhibits the angiogenesis, growth and metastasis of tumors. In its pre-clinical studies, it has shown higher tumor suppression efficacy in multiple cancer models, compared to bevacizumab at the same dose. The Company is currently conducting phase I clinical trials for this product candidate in China and the preliminary results have shown a favourable safety profile and early efficacy signals. The Company expects to initiate phase II/III clinical trials in 2021.

According to F&S, ovarian cancer incidence in China grew at a CAGR of 1.8% from 50.2 thousand in 2015 to 53.9 thousand in 2019 and is expected to further grow at a CAGR of 1.5% from 54.8 thousand in 2020 to 58.1 thousand in 2024. As of 30 Jun 2020, there were two targeted therapy drugs for ovarian cancer approved for sale in China. In addition, there were 12 targeted therapy drug candidates for ovarian cancer pending NDA approval or at clinical stages, among which six are biologics, including the Company's sevacizumab, and five are chemical drugs.

The Company is collaborating with Apexigen on the development and commercialization of sevacizumab in Greater China. Apexigen is entitled to receive upfront payments, milestone payments and royalties from the Company.

PEG-ENDO (Pegylated recombinant human endostatin for injection)

PEG-ENDO is an innovative biologic drug candidate, which the Company has been developing in-house, as an improved version of Endostar, one of the Company's major products. This product candidate enhances the pharmacokinetic properties of recombinant human endostatin by conjugation with a methoxy polyethylene glycol aldehyde, while retaining its biological activities. Pharmacodynamic studies in animal models have demonstrated that this product candidate can significantly enhance the effects of chemotherapy in multiple cancer models when used in combination with chemotherapy drugs. The Company is currently conducting phase Ib (expansion phase) clinical trials for this product candidate in China and expect such clinical trials to be completed in 2021.

CD19 CAR T-cell Therapies

CD19 CAR T-cell therapies are innovative genetically modified cell therapies for the treatment of r/r CD19 positive B-cell non-Hodgkin's lymphoma and r/r CD19 positive B-cell acute lymphoblastic leukemia. Chimeric antigen receptor T cells, or CAR T-cells, represent T cells that have been genetically engineered to express an artificial T-cell receptor and therefore become able to target a specific antigen. As a biomarker for B cells, CD19 is expressed at normal to high levels in a majority of B cell malignancies, including non-Hodgkin's lymphoma and acute lymphoblastic leukemia. CD19 CAR T-cells specifically recognize and target CD19 and kill tumor cells. Investigator-initiated clinical trials for lymphoma have shown a 6-month ORR of 53% and the median PFS of nine months, which are comparable to Yescarta and Kymriah. The Company has obtained the IND approval for its CD19 CAR T-cell therapy candidates and plan to initiate phase I clinical trials in China in 2021. The Company expects to submit the NDA for the candidates in China in 2023.

According to F&S, B-cell CD19-positive acute lymphoblastic leukemia incidence in China grew at a CAGR of 1.6% from 8.8 thousand in 2015 to 9.4 thousand in 2019, and is expected to grow further at a CAGR of 1.5% from 9.6 thousand in 2020 to 10.2 thousand in 2024. Meanwhile, B-cell CD19-positive non-Hodgkin's lymphoma incidence in China grew at a CAGR of 2.6% from 62.3 thousand in 2015 to 69.1 thousand in 2019, and is forecasted to grow further at a CAGR of 2.4% from 70.8 thousand in 2020 to 77.9 thousand in 2024. As of 30 Jun 2020, there were two CAR T-cell therapy drugs approved for sale outside of China with their global sales revenue totalling US$734mn in 2019. As of 30 Jun 2020, there was no CAR T-cell therapy drug approved for sale in China, while there were 16 CAR T-cell therapy drug candidates at clinical stages in China, according to F&S.

Simcere is collaborating with Immunochina on the development and commercialization of such product candidates. The Company entered into a license and collaboration agreement with Immunochina and its affiliates on 27 Mar 2020. Pursuant to the Immunochina License and Collaboration Agreement, Immunochina is responsible for the pre-clinical studies of CD19 CAR T-cell therapies in the Asia-Pacific region, certain investigator-initiated clinical trials of CD19 CAR T-cell therapies in the Greater China, as well as the development, NDA and commercialization of CD19 CAR T-cell therapies outside of the Asia-Pacific region. Simcere is responsible for the IND filings, registrational clinical trials, NDA and commercialization of CD19 CAR T-cell therapies in the Asia-Pacific region, except that Immunochina is responsible for certain IND filings it submitted prior to the Immunochina License and Collaboration Agreement as well as the phase I registrational clinical trials of CD19 CAR T-cell therapies in the Greater China for the indication of r/r CD19 positive non-Hodgkin's lymphoma.

BCMA CAR T-cell Therapy

BCMA CAR T-cell therapy is an innovative genetically modified cell therapy for the treatment of r/r multiple myeloma. BCMA CAR T-cells specifically recognize and target B cell maturation antigen (BCMA), a cell surface protein predominantly expressed on malignant plasma cells, and kill tumor cells. Investigator-initiated clinical trials have shown an ORR of 88% and a CR of over 50% on patients with r/r myeloma. The Company has obtained the IND approval for this product candidate and plans to initiate phase I clinical trials in China soon. The Company expects to submit the NDA for this product candidate in China in 2023.

According to F&S, multiple myeloma incidence in China grew at a CAGR of 3.1% from 18.3 thousand in 2015 to 20.7 thousand in 2019 and is expected to grow further at a CAGR of 2.8% from 21.3 thousand in 2020 to 23.8 thousand in 2024.

Simcere is collaborating with PREGENE on the development and commercialization of this product candidate. The Company entered into a license and collaboration agreement with PREGENE and its affiliates on 27 Feb 2020. Pursuant to the PREGENE License and Collaboration Agreement, PREGENE is responsible for the pre-clinical studies and IND filing of BCMA CAR T-cell therapy in the Greater China, as well as the development, BLA/NDA and commercialization of the same outside of the Greater China. Simcere is responsible for clinical trials and NDA, of BCMA CAR T-cell therapy in the Greater China. Upon receiving regulatory approvals, Simcere will have the exclusive right to commercialize BCMA CAR T-cell therapy in the Greater China.

Autoimmune product candidates

Iguratimod Tablets (Sjögren's syndrome) (艾拉莫德片(干燥综合征))

Iremod (iguratimod tablets), one of the Company's major products, is an innovative chemical drug currently used for the treatment of active rheumatoid arthritis. As iguratimod can inhibit the generation of inflammatory cytokines and stimulate the generation of immunoglobulins, the Company is developing a new indication of iguratimod tablets for treatment of primary Sjögren's syndrome. According to investigator-initiated clinical trials, iguratimod tablets, when used in combination with methylprednisolone, have demonstrated higher efficacy and faster onset than conventional therapy of using hydroxychloroquine in combination with methylprednisolone, without increased incidence of adverse events. Iguratimod tablets have been recommended by the "Primary Sjögren's Syndrome Diagnosis and Treatment Standards" (《原发性干燥综合征诊疗规范》) issued by the Chinese Medical Doctor Association (中国医师协会) in 2020. The Company received IND approval from the NMPA for iguratimod tablets for the indication of Sjögren's syndrome in September 2020.

According to F&S, prevalence of Sjögren's syndrome in China grew from 8.2mn in 2015 to 8.4mn in 2019, and is forecasted to grow further to 8.6mn in 2024.

SIM-335

SIM-335, an innovative chemical drug candidate which the Company has been developing in-house, is intended for the treatment of mild to moderate plaque psoriasis through topical administration. SIM-335 regulates the differentiation of T helper cells 17 and significantly inhibits the secretion and expression of interleukin-17A, an inflammatory cytokine in psoriatic lesions. Meanwhile, SIM-335 inhibits the proliferation of keratinocytes while it also induces their differentiation, facilitates the normalization of epidermal keratinization, reduces the infiltration of inflammatory cells and thereby improves the symptoms and severity of psoriatic lesions. The Company has obtained IND approval for SIM-335 in China and is currently in the preparation for phase I clinical trials.

According to F&S, prevalence of psoriasis in China grew from 6.5mn in 2015 to 6.6mn in 2019, and is forecasted to grow further to 6.8mn in 2024.

SIM-295

SIM-295 is a selective URAT1 inhibitor intended for the treatment of gout with hyperuricemia. URAT1 is a renal urate transporter localized to the apical (brush border) membrane of renal proximal tubular cells, where it mediates the re-absorption of uric acid from the proximal tubule, thereby playing a key role in uric acid homeostasis. By selectively inhibiting the re-absorption of uric acid by URAT1 and increasing the excretion of uric acid, URAT1 inhibitor can significantly control blood uric acid level and show therapeutic effect

on gout. Early-stage clinical trials conducted in South Korea have observed promising efficacy and favourable safety profile. The Company plans to submit the IND application for SIM-295 in China soon.

According to F&S, in recent years, gout prevalence in China has shown an upward trend from 23.9mn in 2015 to 32.0mn in 2019, representing a CAGR of 7.5%, and is forecasted to grow further at a CAGR of 6.1% from 34.2mn in 2020 to 43.3mn in 2024. As of 30 Jun 2020, there was no selective URAT1 inhibitor approved for sale in China. Nevertheless, there were five selective URAT1 inhibitor candidates at clinical stages in China as of 30 Jun 2020.

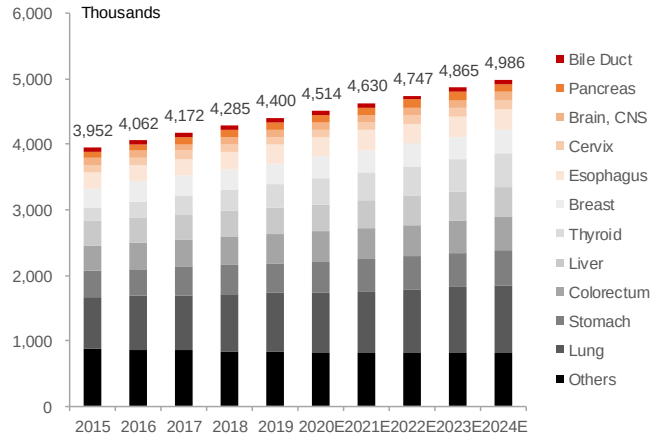
The Company is collaborating with JW Pharmaceutical on the development and commercialization of this product candidate. JW Pharmaceutical has initiated phase IIb clinical trials for SIM-295 in South Korea. Simcere entered into a license agreement with JW Pharmaceutical on 27 Sep 2019 (the “JW Pharmaceutical License Agreement”), pursuant to which the Company was granted an exclusive, sub-licensable and non-transferable right to develop and commercialize a URAT1 inhibitor for therapeutic use in gout with hyperuricemia, namely, SIM-295, in mainland China, Hong Kong and Macau.

Fast-growing oncology market in China

Oncology market overview

Due to increasing stress in life and work, and existence of unhealthy living habits, cancer incidence in China shows an increasing trend as a whole, growing from 4.0mn in 2015 to 4.4mn in 2019 and is expected to reach 5.0mn in 2024.

Figure 8: Incidence by cancer types in China (2015-2024E)



Source: F&S analysis, CMBIS

Among all types of cancer in China, NSCLC has the highest incidence. In 2019, there were 895.3 thousand lung cancer incidence in China, of which 761.0 thousand, or approximately 85%, were recorded as NSCLC. With the improvement of diagnosis and treatment, and the combination of various types of pharmaceuticals, the survival period of NSCLC patients is expected to be prolonged continuously. In conjunction with increases in NSCLC patients and their disposable income, as well as expansion of medical insurance coverage, the demand for NSCLC pharmaceuticals is expected to grow rapidly in the future. Besides, digestive system cancers such as gastric cancer, colorectal cancer, liver cancer, and esophagus cancer also ranked high among all types of cancer in China in terms of incidence in 2019, indicating vast market potential.

The oncology pharmaceutical market in China grew from RMB110.2bn in 2015 to RMB182.7bn in 2019, representing 11.2% of the overall pharmaceutical market in China, and is expected to further grow to RMB367.2bn, or 16.5% of the overall pharmaceutical market in China, in 2024.

The oncology pharmaceutical market in China is expected to continue its growth leveraging several key drivers, including significant unmet clinical demands, increase in patients' affordability and willingness to pay for treatment, favorable government policies to support the development of innovative pharmaceuticals, as well as combination therapies. The oncology pharmaceutical market in China is also expected to be influenced by several trends, including more targeted treatment to oncology diseases, broader application of combination therapies, larger amount of generic pharmaceuticals as well as biosimilars, further inclusion of oncology pharmaceuticals in the NRDL, and longer survival period of oncology patients.

Figure 9: Oncology pharmaceutical market in China (2015-2024E)

Source: F&S analysis, CMBIS

In China, pharmaceuticals used for cancer treatment mainly consist of chemotherapy pharmaceuticals, targeted therapy pharmaceuticals, and immuno-oncology therapy pharmaceuticals, among which chemotherapy pharmaceuticals dominated the entire oncology pharmaceutical market with a market share of 72.6% in 2019, while targeted therapy pharmaceuticals and immuno-oncology therapy pharmaceuticals accounted for 23.4% and 4.0% of the oncology pharmaceutical market, respectively.

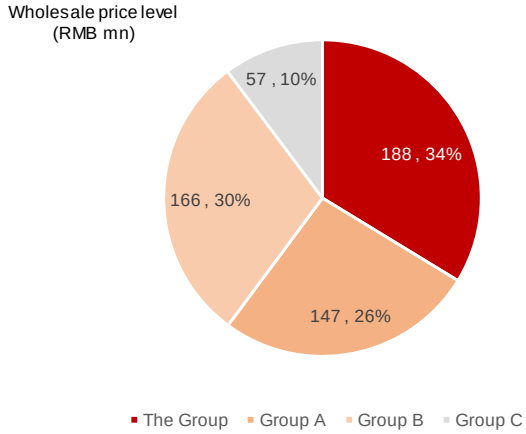
■ Chemotherapy

Chemotherapy uses one or more pharmaceuticals to inhibit DNA synthesis, RNA transcription, protein synthesis, cells division, and/or topoisomerase function, or otherwise kill tumor cells or control their growth.

1) Nedaplatin pharmaceuticals

Platinum-based pharmaceuticals function by binding to DNAs to interfere with their replication, thereby preventing the division and growth of tumor cells. As a second-generation platinum-based pharmaceutical, nedaplatin is more soluble in water and appears to be less toxic to kidney and digestive system compared with cisplatin, the first-generation platinum-based pharmaceutical, and therefore more suitable for elderly patients as well as patients with renal insufficiency. The sales revenue of nedaplatin in China in 2019 totalled RMB558.2mn. With Jepaso (nedaplatin for injection), one of its major products, the Company ranked first in nedaplatin pharmaceutical market in China in terms of sales revenue in 2019.

Figure 10: Competitive landscape of nedaplatin pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

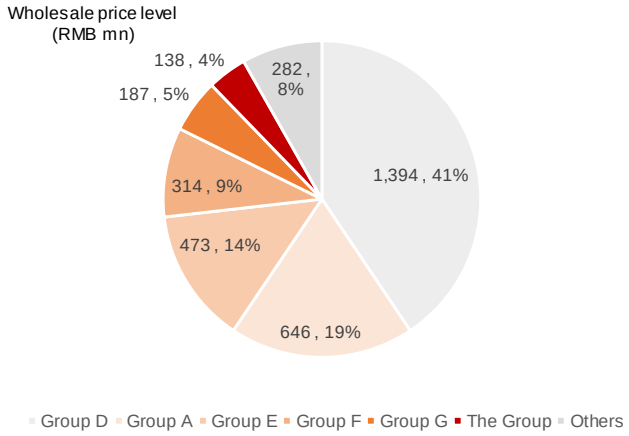
2) Intraoperative chemotherapy pharmaceuticals

Surgery is the major treatment option for various tumors, including digestive system tumors. However, many oncology patients suffer recurrence after resection of the tumor lesions due to intraoperative implantation and metastases of tumor cells. Intraoperative chemotherapy is considered effective in reducing recurrence risks as well as improving prognosis of patients with digestive system tumors. The sales revenue of intraoperative chemotherapy pharmaceuticals for digestive system tumors in China grew from RMB0.7bn in 2015 to RMB2.1bn in 2019, and is expected to grow further at a CAGR of 13.8% from RMB2.5bn in 2020 to RMB4.2bn in 2024. Currently, there are three intraoperative chemotherapy pharmaceuticals available on market in China for treatment of digestive system tumors, namely, lobaplatin, raltitrexed, and 5-fluorouracil implant. Among them, Sinofuan (5-fluorouracil implants), one of Simcere's major products, and the only 5-fluorouracil implant in the market, took up a market share of 6.6% in terms of sales revenue in 2019.

3) Pemetrexed pharmaceuticals

Pemetrexed is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication and thereby prevents the growth of tumor cells. Pemetrexed is suitable as a first-line treatment for NSCLC and malignant pleural mesothelioma. The sales revenue of pemetrexed pharmaceuticals in China grew from RMB2.4bn in 2015 to RMB3.4bn in 2019, representing a CAGR of 9.5%, and is expected to grow further at a CAGR of 10.7% from RMB3.4bn in 2020 to RMB5.1bn in 2024. With Jiebaili (pemetrexed disodium for injection), one of its major products, the Company ranked sixth in pemetrexed pharmaceutical market in China in terms of sales revenue in 2019.

Figure 11: Competitive landscape of pemetrexed pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

■ Targeted therapies

Targeted therapy typically uses small-molecule pharmaceuticals or monoclonal antibodies to target identified drivers of cancer growth, which could be protein molecules inside tumor cells or gene segments, at the cellular and molecular level.

1) Targeted therapy pharmaceuticals for NSCLC

Based on the size of tumor, lymph node infiltration by cancer cells and conditions of metastasis, lung cancer can be classified into multiple stages. While surgery, chemotherapy and radiotherapy are optimal treatment options for stage I to stage III NSCLC patients, targeted therapy is primarily involved in treatment of patients with initial or recurrent stage III/IV NSCLC. In China, the sales revenue of targeted therapy drug for NSCLC grew rapidly from RMB5.3bn in 2015 to RMB20.8bn in 2019, representing a CAGR of 40.8%, and is expected to grow further at a CAGR of 27.1% from 2020 to 2024, reaching RMB77.1bn in

2024. Among all categories of targeted pharmaceuticals for NSCLC in China, recombinant human endostatin ranked seventh in terms of sales revenue in 2019 with a market share of 5.9%. Endostar (recombinant human endostatin injection), one of the Company's major products, is the only recombinant human endostatin approved for sale in China. In addition, the Company is currently conducting the phase Ib (expansion phase) clinical trials for PEG-ENDO, which enhances pharmacokinetic properties of Endostar, expecting it to help the Company further expand market share in the market of targeted pharmaceuticals for NSCLC in China. The Company is also conducting the pivotal registrational trials for bevacizumab biosimilar product candidate for treatment of advanced non-squamous NSCLC.

2) Targeted therapy pharmaceuticals for ovarian cancer

In recent years, ovarian cancer incidence in China shows an upward trend from 50.2 thousand in 2015 to 53.9 thousand in 2019, and is forecasted to grow further at a CAGR of 1.5% from 54.8 thousand in 2020 to 58.1 thousand in 2024, indicating increasing market demand for relevant pharmaceuticals.

As of 30 Jun 2020, there were two targeted pharmaceuticals for ovarian cancer approved for sale in China. In addition, there were 12 targeted pharmaceutical candidates for ovarian cancer pending NDA approval or at clinical stages in China as of 30 Jun 2020, among which six are biologics and six are chemical drugs. The Company is currently conducting the phase I clinical trials in China for sevacizumab, a biological pharmaceutical candidate for treatment of ovarian cancer that targets the pro-angiogenic function of VEGF and thereby inhibits the angiogenesis, growth and metastasis of tumors.

3) Targeted therapy pharmaceuticals for solid tumors

NTRK gene fusion leads to abnormal proteins that may induce tumor cell proliferation and constitutively activate downstream oncogenic signaling pathways. As a potential treatment option for various solid tumors driven by NTRK gene fusion, NTRK small molecule inhibitor functions by inhibiting the kinase activity of NTRK. As of 30 Jun 2020, there was no NTRK small molecule inhibitor approved for sale in China and four NTRK small molecule inhibitor candidates were at clinical stages in China. The Company has a multi-kinase (including NTRK) inhibitor candidate and has submitted the IND application for this product candidate in China.

■ **Immuno-oncology therapies**

Immuno-oncology therapy aims to stimulate a person's immune system in order to more effectively treat cancer. Immuno-oncology therapy is able to provide durable remission and is well-tolerated in advanced oncology patients, therefore, it is considered a revolutionary therapy for oncology treatment. Immuno-oncology therapies mainly include cell therapies, immune checkpoint monoclonal antibodies, therapeutic cancer vaccines, and cytokines. The market size of immuno-oncology therapies in China grew rapidly from RMB0.7bn in 2015 to RMB7.4bn in 2019, and is expected to grow further at a CAGR of 59.9% from RMB15.0bn in 2020 to RMB97.9bn in 2024.

1) CAR T-cell therapy products

A majority of immune oncology therapies achieve antineoplastic effect through T cells. Chimeric antigen receptor T cells, or CAR T-cells, represent T cells that have been genetically engineered to express an artificial T-cell receptor and therefore become able to target a specific antigen. CAR T-cell therapy makes use of such T cells for oncology treatment and shows better clinical efficacy and long-lasting effect with shorter treatment duration.

As of 30 Jun 2020, there were two CAR T-cell therapy products approved for sale outside of China with their global sales revenue totaled US$734mn in 2019. As of 30 Jun 2020, there was no CAR T-cell therapy product approved for sale in China, while there were 16 CAR T-cell therapy product candidates at clinical stages in China. The Company has obtained IND approvals and expects to initiate the phase I clinical trials for three CAR T-cell therapy product candidates in China in the second half of 2020.

2) Anti-PD-1/PD-L1 therapy pharmaceuticals

PD-1 is a protein found on T cells which, when binding to PD-L1 (the ligand of PD-1), leads to T-cell anergy and blocks antitumor immune responses. PD-1/PD-L1 monoclonal antibodies are immune checkpoint inhibitors which target PD-1 and PD-L1, and function by blocking the binding between PD-1 and PD-L1, recovering the function of T cells, and consequently boosting immune responses to tumor cells. PD-1/PD-L1 monoclonal antibodies have shown higher therapeutic efficacy on various oncology indications and have fewer side effects compared to chemotherapy pharmaceuticals. The sales revenue of PD-1/PD-L1 monoclonal antibodies in China in 2019 totaled RMB6.3bn, and is expected to grow rapidly at a CAGR of 56.1% from RMB13.8bn in 2020 to RMB81.9bn in 2024.

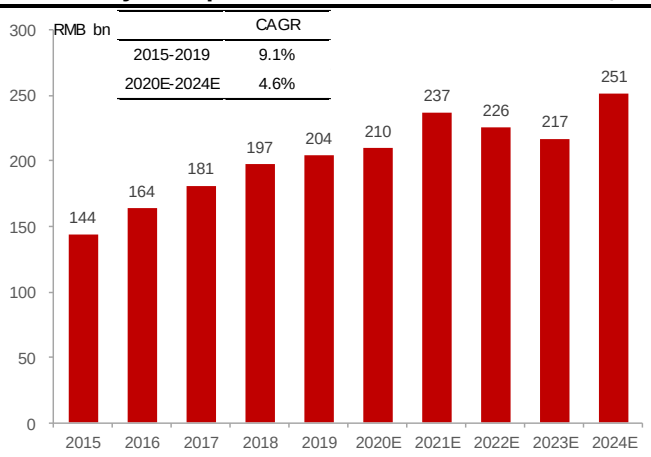
As of 30 Jun 2020, there were eight PD-1/PD-L1 monoclonal antibodies approved for sale in China. The Company has obtained the exclusive promotion right in respect of oncology treatment indications of a PD-L1 inhibitor known as KN035 in China. Its collaboration partners are currently conducting phase II clinical trials of KN035 for dMMR/MSI-H colorectal carcinoma and other advanced solid tumors and phase III clinical trials for advanced BTC in mainland China as well as phase I clinical trials in the US and Japan. Meanwhile, KN035 is undergoing phase I clinical trials in the US and Japan. The Company is currently conducting pre-clinical studies on combination therapy candidates with KN035 for treatment of solid tumors.

Central nervous system pharmaceutical market

Central nervous system, a part of nervous system, consists of brain and spinal cord and controls awareness, sensations, thoughts, and movements of the body. Central nervous system diseases refer to a group of neurological disorders that affect the structure or function of brain or spinal cords, primarily include neurodegeneration, functional disorders, structural disorders, central nervous system infections, and demyelinating diseases.

Due to high prevalence rate of central nervous system diseases in China, market demand for relevant pharmaceuticals has become huge. The sales revenue of central nervous system pharmaceuticals in China grew from RMB144.0bn in 2015 to RMB204.3bn in 2019, representing a CAGR of 9.1%, and is expected to grow further at a CAGR of 4.6% from 2020 to 2024, reaching RMB250.9bn in 2024.

Figure 12: Central nervous system pharmaceutical market in China, 2015-2024E



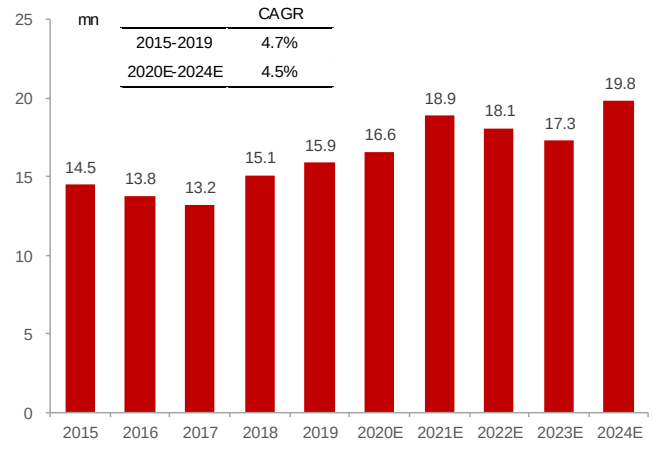
Source: F&S analysis, CMBIS

■ Neuroprotection following stroke

Stroke is one of the major central nervous system diseases which occurs when a blood vessel that carries oxygen and nutrients to brain is blocked by a clot or bursts, therefore disrupting the flow of blood carrying essential oxygen and resulting in the death of nerve cells. Patients with acute ischemic stroke need to receive specific treatments. In particular, compared to thrombolytic therapies which improves cerebral blood circulation of patients, statins and neuroprotective pharmaceuticals can improve prognosis of patients, thereby minimizing potential damage as well as recurrence risk.

In China, the prevalence of stroke grew at a CAGR of 4.7% from 13.2mn in 2015 to 15.9mn in 2019, and is expected to continue to grow at a CAGR of 4.5% from 16.6mn in 2020 to 19.8mn in 2024, indicating increasing market demand for relevant pharmaceuticals.

Figure 13: Prevalence of stroke in China, 2015-2024E

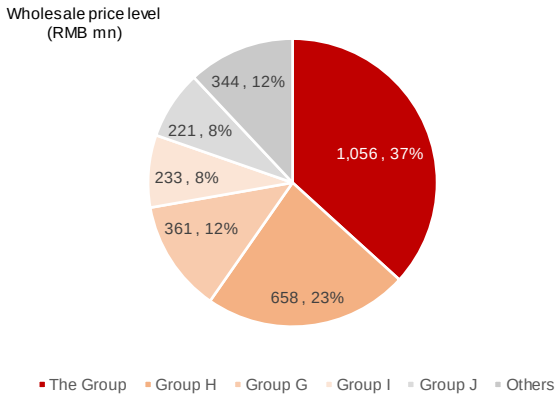


Source: F&S analysis, CMBIS

Commonly-used neuroprotective pharmaceuticals primarily include calcium channel blockers, free radical scavengers, membrane stabilizing agents, glutamate antagonists. The representative pharmaceutical of free radical scavengers is edaravone, which accounted for 11.6% of the neuroprotective pharmaceutical market in China in terms of sales revenue in 2019. Since 2015, local governments in China have successively issued policies to regulate the usage of ancillary pharmaceuticals in medical institutions.

In June 2019, the Chinese government issued the "First Batch of National Key Drug List for Monitoring and Prescription Control (Chemicaland Biological Products)" (《第一批国家重点监控合理用药药品目录(化药和生物制品)》) which included neuroprotective pharmaceuticals. Similar to the overall neuroprotective pharmaceutical market, edaravone pharmaceutical market in China has also experienced shrinkage since 2016. The sales revenue of edaravone in China in 2019 totaled RMB2.9bn, of which RMB1.1bn was generated by Bicun (edaravone injection), one of the Company's major products. With a market share of 36.8%, the Company ranked first in edaravone pharmaceutical market in China in terms of sales revenue in 2019. It also holds a leading position in neuroprotective pharmaceutical market in China.

Figure 14: Competitive landscape of edaravone pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

In recent years, the prevalence of stroke increased year by year in China, indicating increasing market demand for relevant pharmaceuticals. Meanwhile, the restricted clinical use of neuroprotective pharmaceuticals led to a decrease in the prescription for pharmaceuticals for treatment of stroke, therefore releasing vast market potential for innovative pharmaceuticals with an intended indication of stroke. As of 30 Jun 2020, there were 12 pharmaceutical candidates for treatment of stroke at clinical stages or pending NDA approval in China, two of which were developed by Simcere. In particular, the Company received NMPA's approval for edaravone and dexborneol concentrated solution for injection, a category I innovative drug in July 2020. It is the only pharmaceutical for the treatment of stroke to obtain approval for sale in the past five years worldwide. The Company is also conducting the phase I clinical trials for Y-2 sublingual tablets in China.

■ **Cerebral edema**

Cerebral edema, a severe clinical complication of acute ischemic stroke, refers to life-threatening swelling of the brain due to excess accumulation of fluid in intracellular or extracellular spaces of the brain. Clinically significant cerebral edema requires medical intervention. Incidence of clinically significant cerebral edema in China grew from 551.3 thousand in 2015 to 677.5 thousand in 2019, and is expected to grow further at a CAGR of 3.1% from 2020 to 2024, reaching 793.4 thousand in 2024. In China, commonly-used pharmaceuticals for treatment of cerebral edema caused by acute ischemic stroke include mannitol, glycerol fructose, and furosemide.

Aquaporin-4 (AQP4) inhibitor is a potential option for treatment and control of cerebral edema. Aquaporins are membrane proteins in the membrane of biological cells, mainly facilitating transportation of water between cells, while AQP4, a subtype of aquaporin, contributes most to brain fluid regulation. AQP4 inhibitor functions by decreasing expression level of AQP4 and thereby treating and controlling cerebral edema. As of 30

Jun 2020, there was no AQP4 inhibitor approved for sale worldwide, and no AQP4 inhibitor was under clinical research in China. Therefore, it is expected to be a first-in-class innovative pharmaceutical. The Company has an AQP4 inhibitor candidate, and is currently preparing for IND application for this product candidate and expect to initiate phase I clinical trials in China in 2021.

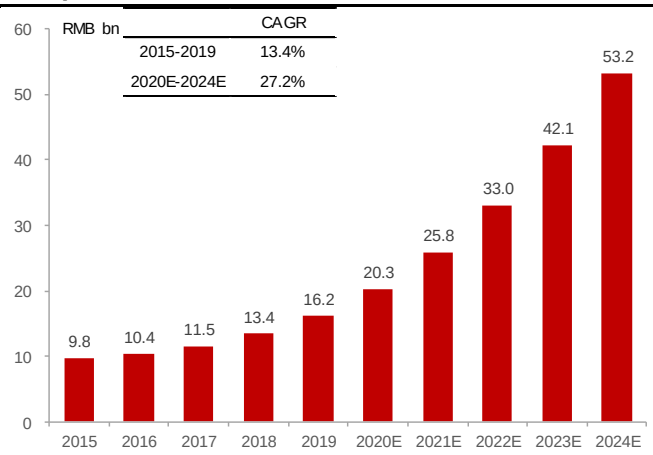
Autoimmune pharmaceutical market

Autoimmune diseases occur when the immune system mistakenly attacks a person's own tissues and organs. There are approximately 100 types of autoimmune disorders, which can affect substantially all parts of human body, including brain, heart, nerves, blood vessels, eyes, lungs, kidneys, glands, digestive tract, joints, muscles, and skin. Based on the targeted antigen, autoimmune diseases can be classified into systemic ones where immune system attacks self-antigens in several organs, and organ-specific ones where immune response targets antigens in a single organ.

While systemic immunosuppressive therapy broadly suppresses immune activation, and is considered the major clinical treatment option for autoimmune diseases, all currently available therapies do not cure autoimmune diseases and also cause a variety of side effects, including infections, hematological system impairment, bone mineral density loss, glucose intolerance, metabolic imbalance, and psychiatric disturbance.

With the increases in prevalence of autoimmune diseases, sales revenue of the relevant pharmaceuticals in China grew from RMB9.8bn in 2015 to RMB16.2bn in 2019, and is expected to grow rapidly at a CAGR of 27.2% from 2020 to 2024, reaching RMB53.2bn in 2024.

Figure 15: Autoimmune pharmaceutical market in China, 2015-2024E



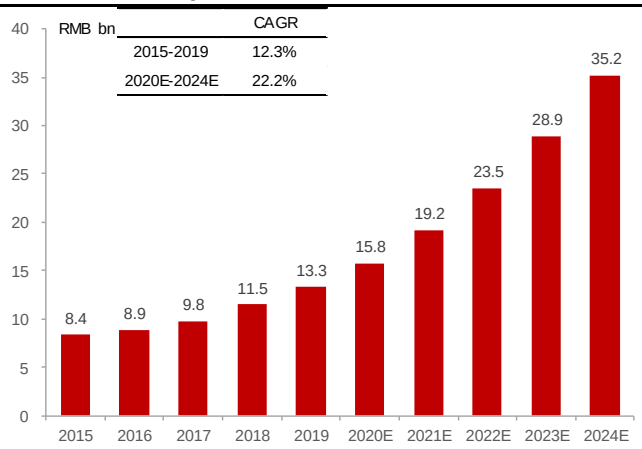
Source: F&S analysis, CMBIS

■ Rheumatoid arthritis

Rheumatoid arthritis is a long-term systemic autoimmune disorder characterized by chronic inflammation in the synovium of joints and pannus formation in joint cavities, leading to destruction of both cartilaginous and bony elements of joints and eventually resulting in joint stiffness, tumidness, pain, deformity, and destruction. Although there is no cure for rheumatoid arthritis, clinical studies have indicated that long-term and routine use of DMARDs at early stage of diseases can alleviate symptoms as well as postpone the progression of diseases. In the event of failure of pharmaceutical treatment, patients may receive surgeries to repair, reconstruct or replace damaged joints.

In China, the prevalence of rheumatoid arthritis grew at a CAGR of 0.6% from 5.8mn in 2015 to 5.9mn in 2019, and is expected to continue to grow at a CAGR of 0.7% from 6.0mn in 2020 to 6.1mn in 2024. Meanwhile, the sales revenue of rheumatoid arthritis pharmaceuticals in China increased rapidly from RMB8.4bn in 2015 to RMB13.3bn in 2019, representing a CAGR of 12.3%, and is expected to increase further at a CAGR of 22.2% from 2020 to 2024, reaching RMB35.2bn in 2024.

Figure 16: Rheumatoid arthritis pharmaceutical market in China, 2015-2024E



Source: Company data, CMBIS

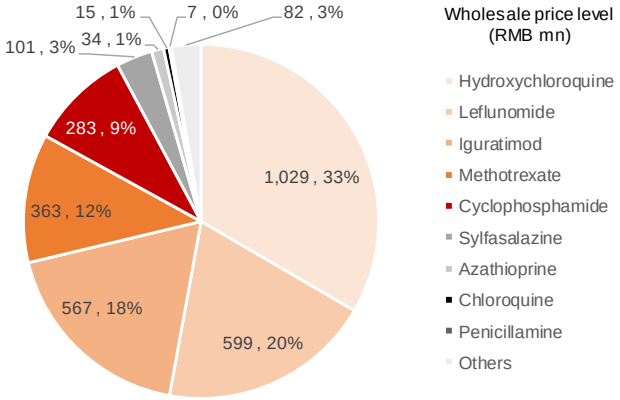
Currently, pharmaceuticals for treatment of rheumatoid arthritis include conventional synthetic DMARDs, other DMARDs (mainly comprising biological DMARDs and targeted synthetic DMARDs), glucocorticoid, and non-steroidal anti-inflammatory pharmaceuticals. Conventional synthetic DMARDs and targeted synthetic DMARDs are collectively referred to as small molecule DMARDs.

1) Conventional synthetic DMARDs

Conventional synthetic DMARDs are widely recognized as the first-line therapy pharmaceuticals for rheumatoid arthritis. The sales revenue of conventional synthetic DMARDs in China grew from RMB1.9bn in 2015 to RMB3.1bn in 2019, representing a CAGR of 12.4%, and is forecasted to grow further at a CAGR of 11.2% from RMB3.8bn in 2020 to RMB5.8bn in 2024.

Commonly-used conventional synthetic DMARDs mainly include methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, and iguratimod. Iremod (iguratimod tablets), one of the Company's major products and the only iguratimod drug in the market, took up a market share of 18.4% in terms of sales revenue in China in 2019.

Figure 17: Competitive landscape of conventional synthetic DMARDs market in China, 2019

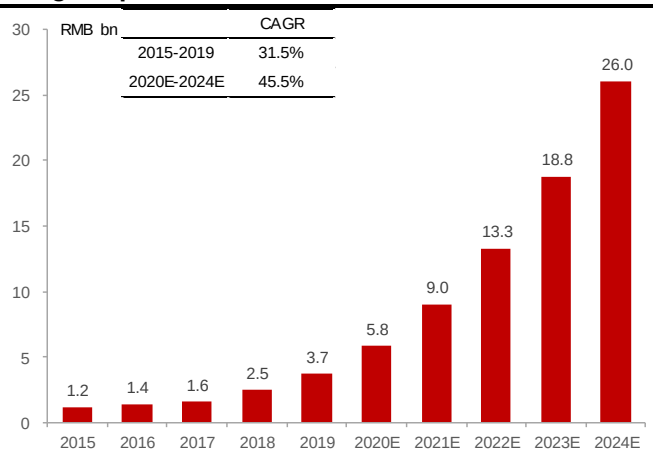


Source: F&S analysis, CMBIS

2) Other DMARDs

Other DMARDs mainly consist of biological DMARDs and targeted synthetic DMARDs, both of which are effective in alleviating symptoms for, and may suppress joint damage and deformities of, patients with moderate or severe active rheumatoid arthritis. Other DMARDs mainly include tocilizumab, adalimumab, golimumab, infliximab, etanercept, tofacitinib, and baricitinib. Biological DMARDs are part of biological pharmaceuticals for treatment of autoimmune diseases, the sales revenue of which grew at a CAGR of 31.5% from RMB1.2bn in 2015 to RMB3.7bn in 2019, and is expected to grow rapidly at a CAGR of 45.5% from RMB5.8bn in 2020 to RMB26.0bn in 2024 in China, indicating vast market potential.

Figure 18: Market of biological pharmaceuticals for autoimmune diseases in China, 2015-2024E



Source: F&S analysis, CMBIS

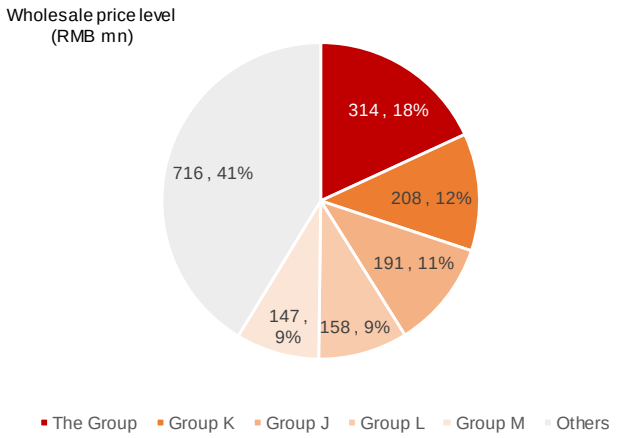
T-cell activation is considered to be one of the core pathogenesis of rheumatoid arthritis. Abatacept injection, the first and only CTLA4-Fc fusion protein approved for sale in China and the first and only selective T-cell co-stimulation modulator in the autoimmune disease therapeutic area worldwide, is a new type of biological DMARDs with a unique mechanism of action which prevents activation of T cells by binding to the natural ligands CD80 and CD86 on antigen-presenting cells, thereby blocking their interaction with CD28 on the T cells, and consequently reduces inflammation. According to another head-to-head comparison study in 2019, abatacept injection shows higher efficacy among HLA-DRB1 SE-positive patients compared with adalimumab. In China, the prevalence of HLA-DRB1 SE-positive rheumatoid arthritis was 4.7mn in 2019.

3) Non-steroidal Anti-inflammatory Pharmaceuticals

Non-steroidal anti-inflammatory pharmaceuticals can be used to reduce acute inflammation caused by rheumatoid arthritis, therefore alleviating pain and improving function of involved joint. For patients with moderate or severe active rheumatoid arthritis, nonsteroidal anti-inflammatory pharmaceuticals can be used in combination with DMARDs. Non-steroidal anti-inflammatory pharmaceuticals are also widely used for treatment of pains caused by other diseases, such as osteoarthritis, migraine, and periodontitis.

The sales revenue of non-steroidal anti-inflammatory pharmaceuticals in China grew from RMB13.1bn in 2015 to RMB21.8bn in 2019, representing a CAGR of 13.6%, and is forecasted to grow further at a CAGR of 12.0% from RMB24.8bn in 2020 to RMB39.0bn in 2024. Non-steroidal anti-inflammatory pharmaceuticals mainly include aspirin, ibuprofen, celecoxib, and diclofenac sodium. The Company ranked first in mono-ingredient diclofenac sodium pharmaceutical market in China in terms of sales revenue in 2019, with a market share of 18.1%.

Figure 19: Competitive landscape of mono-ingredient diclofenac sodium pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

■ Gout

Gout is a common but complex form of metabolic disease caused by disruption of metabolism of uric acid. When uric acid crystals accumulate in joints, gouty arthritis may occur. In recent years, gout prevalence in China has shown an upward trend from 23.9mn in 2015 to 32.0mn in 2019, and is forecasted to grow further at a CAGR of 6.1% from 34.2mn in 2020 to 43.3mn in 2024.

Selective URAT1 inhibitor is a new treatment option for gout. It functions by selectively inhibiting the re-absorption of uric acid by URAT1 and increasing the excretion of uric acid, thereby significantly controlling blood uric acid level. As of 30 Jun 2020, there was no selective URAT1 inhibitor approved for sale in China, while only five selective URAT1 inhibitor candidates were at clinical stages in China. The Company plans to submit the IND application for its URAT1 inhibitor candidate in China soon.

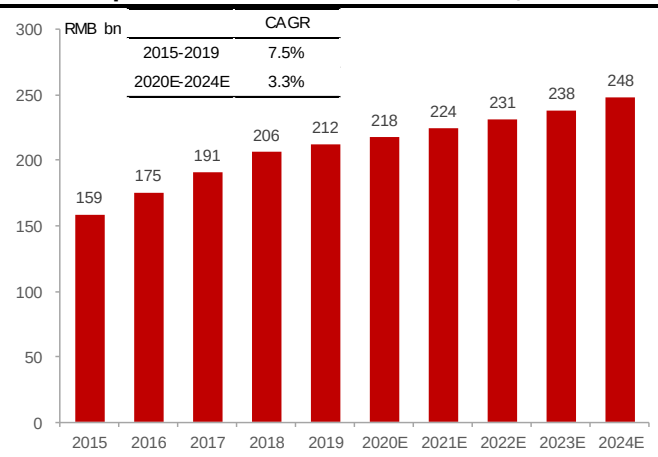
Other therapeutic areas

In addition to the aforementioned three therapeutic areas, the Company commercializes or develops therapies in cardiovascular and infectious diseases, among others.

■ Cardiovascular pharmaceutical market in China

Cardiovascular diseases refer to a class of diseases that involve heart or blood vessels, mainly including coronary artery disease, rheumatic heart disease, congenital heart disease, peripheral arterial disease, and cerebrovascular disease. Due to increasing prevalence of cardiovascular diseases, market size of relevant pharmaceuticals in China grew from RMB 158.8bn in 2015 to RMB212.2bn in 2019, representing a CAGR of 7.5%, and is expected to grow further at a CAGR of 3.3% from RMB217.5bn in 2020 to RMB247.7bn in 2024.

Figure 20: Cardiovascular pharmaceutical market in China, 2015-2024E



Source: F&S analysis, CMBIS

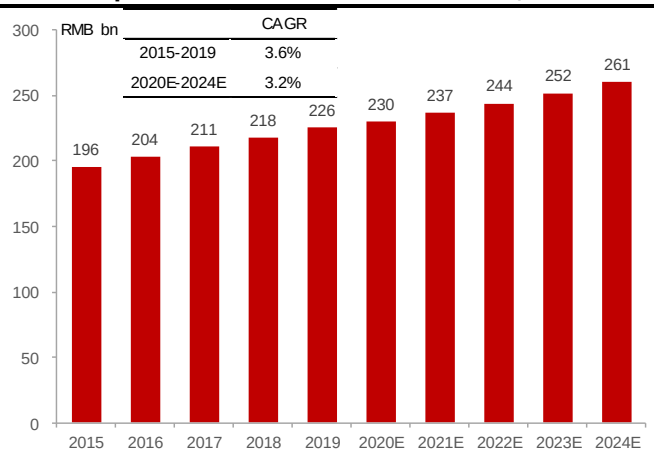
Hypercholesterolemia is a common cardiovascular disease. Due to ageing population and unhealthy diet, the prevalence of hypercholesterolemia has been increasing in recent years, showing increasing market demand for relevant pharmaceuticals. Statins are the most commonly-used cholesterol-lowering pharmaceuticals, and rosuvastatin, as a third-generation statin, shows high potency with superior safety profile. The sales revenue of rosuvastatin in China in 2019 totaled RMB6.8bn. With Softan (rosuvastatin calcium tablets), one of its major products, the Company ranked fifth in rosuvastatin pharmaceutical market in China in terms of sales revenue in 2019 with a market share of 5.4%.

Hypertension is a long-term medical condition in which the blood pressure in the arteries is persistently elevated which results in damage to end organs such as the eyes, kidney, heart, blood vessels and others. The prevalence of hypertension in China increased from 289.9mn in 2015 to 317.4mn in 2019, representing a CAGR of 2.3%, and is expected to grow further at a CAGR of 2.0% from 324.4mn in 2020 to 351.4mn in 2024. Currently, the Company markets and/or sells OLMETEC PLUS (olmesartan medoxomil and hydrochlorothiazide tablets), which is developed and manufactured by Daiichi Sankyo.

■ Anti-infective pharmaceutical market in China

Infectious diseases are disorders caused by organism invasion of human body. After organisms enter into human body, they reproduce and release toxin, and stimulate host tissues to react. Anti-infectives are pharmaceuticals used for treatment of infectious diseases. In China, the sales revenue of anti-infectives increased from RMB195.8bn in 2015 to RMB225.5bn in 2019, and is forecasted to further increase at a CAGR of 3.2% from 2020 to 2024, reaching RMB260.7bn in 2024.

Figure 21: Anti-infective pharmaceutical market in China, 2015-2024E

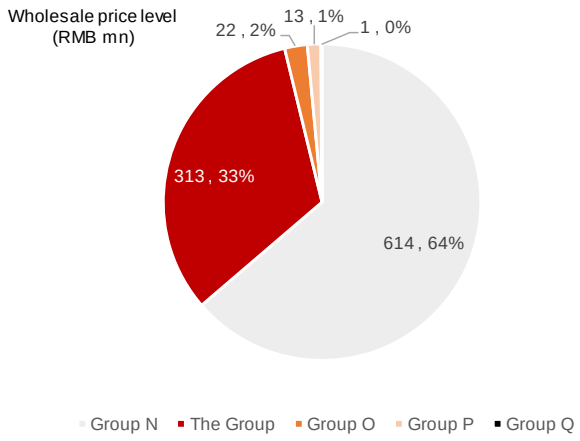


Source: F&S analysis, CMBIS

Anti-infectives can be classified into antifungals, antibacterials, antivirals and other types of anti-infectives, among which, antibacterials account for the largest portion of the overall anti-infectives market in China in terms of sales revenue.

Carbapenem is a commonly-used antibacterial for treatment of severe or high-risk bacterial infections. In 2019, the carbapenem drug market in China totaled RMB8.1bn, and biapenem drug market accounted for a market share of 11.9%, totaling RMB1.0bn. With Newanti (biapenem for injection), one of its major products, the Company is the second largest player in the biapenem drug market in China in terms of sales revenue in 2019, with a market share of 32.5%.

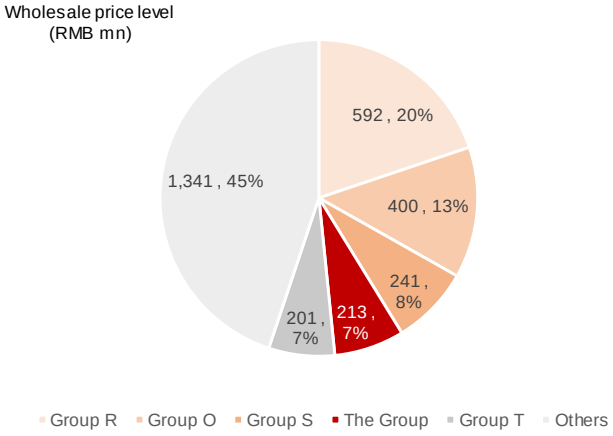
Figure 22: Competitive landscape of biapenem pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

Amoxicillin is an antibacterial that can be used to treat various bacterial infections. In 2019, the mono-ingredient amoxicillin drug market in China totaled RMB3.0bn, and the Company ranked fourth in terms of sales revenue with a market share of 7.1%.

Figure 23: Competitive landscape of mono-ingredient amoxicillin pharmaceutical market in China, 2019



Source: F&S analysis, CMBIS

Financial analysis

Strong growth in coming years

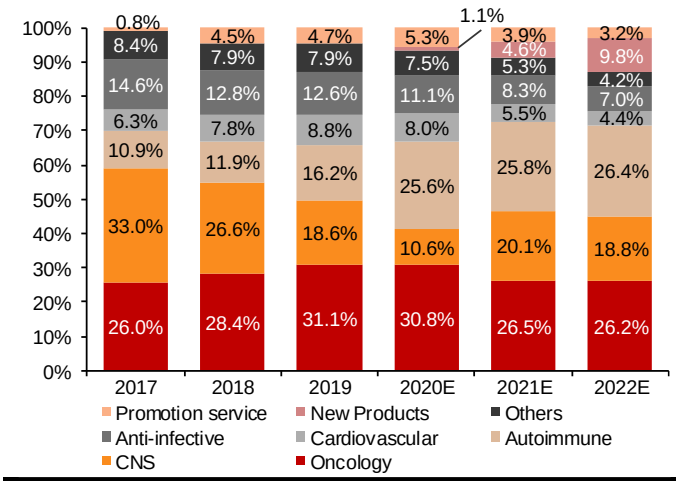
We forecast total revenue to reach RMB4,554mn/ RMB6,458mn/ RMB8,164mn in FY2020E/21E/22E, representing a YoY of -10%/42%/26%, respectively. We forecast sales of oncology, CNS and autoimmune drugs to contribute 26%,19% and 26% of Simcere's total revenue in FY22E, respectively.

Figure 24: Revenue forecasts (2018-22E)

(YE 31 Dec) (RMBmn)	2018	2019	2020E	2021E	2022E
Sales of pharmaceutical products	4,309	4,800	4,311	6,207	7,906
YoY	*12.3%*	*11.4%*	*-10.2%*	*44.0%*	*27.4%*
-Oncology	1,280	1,569	1,404	1,709	2,142
-YoY	*27.4%*	*22.6%*	*-10.5%*	*21.7%*	*25.3%*
-CNS	1,202	937	481	1,297	1,538
-YoY	*-5.8%*	*-22.1%*	*-48.7%*	*169.6%*	*18.6%*
-Autoimmune	538	814	1,167	1,669	2,159
-YoY	*27.1%*	*51.3%*	*43.5%*	*42.9%*	*29.4%*
-Cardiovascular	353	445	365	356	359
-YoY	*45.0%*	*26.2%*	*-18.0%*	*-2.5%*	*1.0%*
-Anti-infective	579	636	504	537	568
-YoY	*2.6%*	*9.7%*	*-20.8%*	*6.6%*	*5.8%*
-Others	357	400	340	340	340
-YoY	*9.9%*	*12.0%*	*-15.0%*	*0.0%*	*0.0%*
Promotion service income	205	236	243	251	258
YoY	*563.0%*	*15.3%*	*3.0%*	*3.0%*	*3.0%*
Total revenue (RMB mn)	**4,514**	**5,037**	**4,554**	**6,458**	**8,164**
YoY	*16.7%*	*11.6%*	*-9.6%*	*41.8%*	*26.4%*

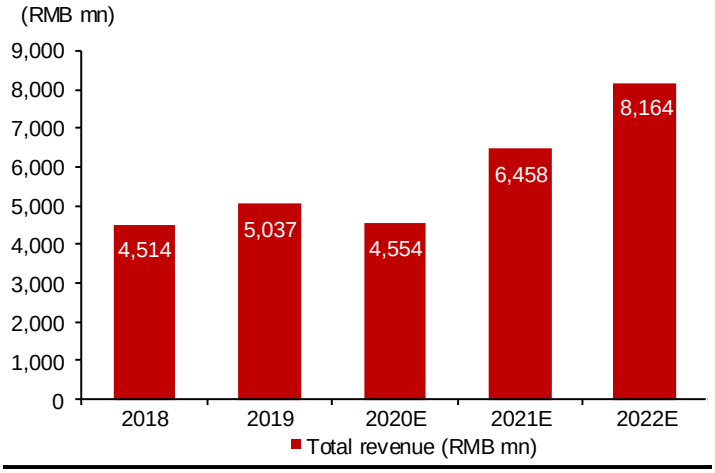
Source: Company data, CMBIS estimates

Figure 25: Revenue breakdown



Source: Company data, CMBIS estimates

Figure 26: Total revenue forecasts



Source: Company data, CMBIS estimates

Simcere recorded attributable profit of RMB734mn/ RMB1,004mn in FY18A/19A. We expect its net profit to be RMB684mn/ RMB1,150mn/ RMB1,453mn in FY20E/21E/22E.

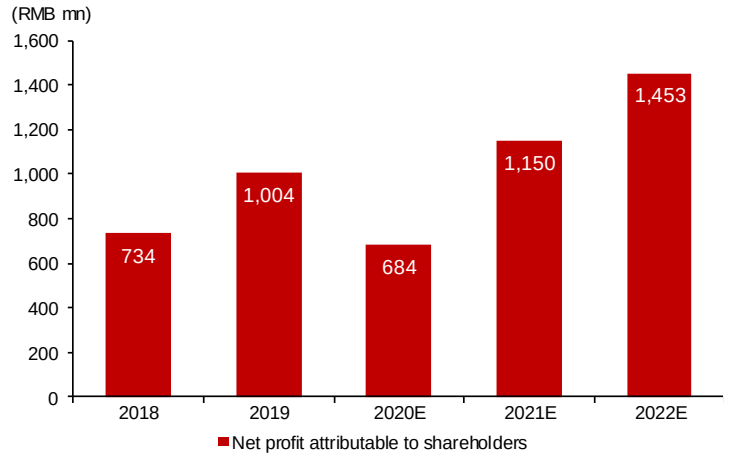
We forecast selling and distribution expenses ratio to steadily maintain at 40.5%/40.0%/40.0% in FY20E/21E/22E and expect admin expense ratio to decrease to 7.0%/6.9%/6.8% in FY20E/21E/22E.

Figure 27: P&L forecasts

(YE 31 Dec) (RMB mn)	2018	2019	2020E	2021E	2022E
Revenue	**4,514**	**5,037**	**4,554**	**6,458**	**8,164**
YoY	*16.7%*	*11.6%*	*-9.6%*	*41.8%*	*26.4%*
Cost of sales	(771)	(888)	(820)	(1,130)	(1,429)
% of revenue	*-17.1%*	*-17.6%*	*-18.0%*	*-17.5%*	*-17.5%*
Gross profit	**3,743**	**4,148**	**3,734**	**5,328**	**6,735**
GPM	*82.9%*	*82.4%*	*82.0%*	*82.5%*	*82.5%*
Other income	68	92	90	90	90
% of revenue	*1.5%*	*1.8%*	*2.0%*	*1.4%*	*1.1%*
Other net (loss)/gain	91	16	0	0	0
% of revenue	*2.0%*	*0.3%*	*0.0%*	*0.0%*	*0.0%*
R&D expenses	(447)	(716)	(820)	(1,033)	(1,306)
% of revenue	*-10%*	*-14%*	*-18%*	*-16%*	*-16%*
Administrative expenses	(290)	(352)	(319)	(446)	(555)
% of revenue	*-6.4%*	*-7.0%*	*-7.0%*	*-6.9%*	*-6.8%*
Selling and distribution expenses	(2,222)	(2,016)	(1,844)	(2,583)	(3,266)
% of revenue	*-49.2%*	*-40.0%*	*-40.5%*	*-40.0%*	*-40.0%*
Finance cost, net	(11)	(81)	(48)	(26)	(1)
% of revenue	*-0.2%*	*-1.6%*	*-1.0%*	*-0.4%*	*0.0%*
Profit before tax	**929**	**1,082**	**786**	**1,321**	**1,690**
PBT margin	*20.6%*	*21.5%*	*17.3%*	*20.5%*	*20.7%*
Income tax expense	(195)	(78)	(102)	(172)	(237)
% tax rate	*21.0%*	*7.2%*	*13.0%*	*13.0%*	*14.0%*
Total net profit	734	1,004	684	1,150	1,453
Minority Interests	*0*	*0*	*0*	*0*	*0*
Net profit attributable to shareholders	**734**	**1,004**	**684**	**1,150**	**1,453**
NPM	*16.3%*	*19.9%*	*15.0%*	*17.8%*	*17.8%*
YoY	*109.4%*	*36.8%*	*-31.9%*	*68.1%*	*26.4%*

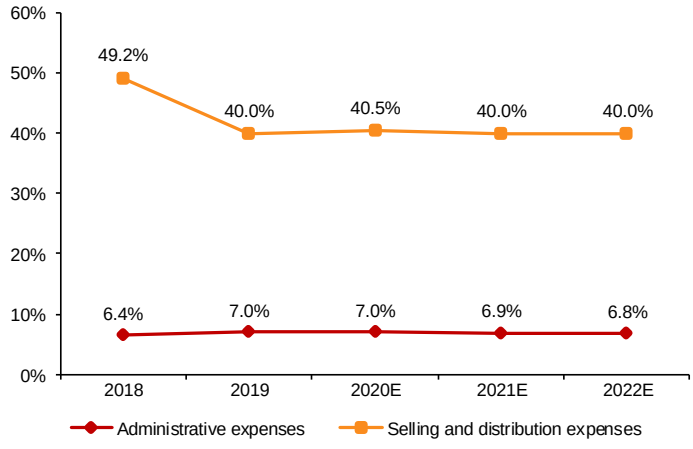
Source: Company data, CMBIS estimates

Figure 28: Net profit forecasts



Source: Company data, CMBIS estimates

Figure 29: SG&A expense ratio forecasts



Source: Company data, CMBIS estimates

Financial Statements

Income statement

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	**4,514**	**5,037**	**4,554**	**6,458**	**8,164**
Sales of pharmaceutical products	4,309	4,800	4,311	6,207	7,906
Promotion service income	205	236	243	251	258
Cost of sales	(771)	(888)	(820)	(1,130)	(1,429)
Gross profit	**3,743**	**4,148**	**3,734**	**5,328**	**6,735**
Other income	68	92	90	90	90
Other expenses	91	16	0	0	0
Other net (loss)/gain	(447)	(716)	(820)	(1,033)	(1,306)
R&D expenses	(447)	(716)	(820)	(1,033)	(1,306)
Administrative expenses	(290)	(352)	(319)	(446)	(555)
Listing expenses	0	0	0	0	0
Finance cost	(48)	(116)	(106)	(86)	(66)
Profit before tax	**929**	**1,082**	**786**	**1,321**	**1,690**
Income tax expense	(195)	(78)	(102)	(172)	(237)
Total net profit	**734**	**1,004**	**684**	**1,150**	**1,453**
Minority Interests	0	0	0	0	0
Profit attributable to shareholders	**734**	**1,004**	**684**	**1,150**	**1,453**

Cash flow summary

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Profit before tax	**929**	**1,082**	**786**	**1,321**	**1,690**
Depreciation for plant and equipment	103	147	140	145	149
Change in working capital	(210)	(556)	(64)	(475)	(479)
Others	108	365	168	216	255
Tax paid	(155)	(265)	(102)	(172)	(237)
Net cash from operating activities	**776**	**773**	**927**	**1,036**	**1,378**
Capex	(335)	(508)	(200)	(200)	(200)
Acquisition of subsidiaries	0	0	0	0	0
Other investing activities	(137)	(85)	58	59	65
Net cash from investing activities	**(472)**	**(593)**	**(142)**	**(141)**	**(135)**
Net proceeds from shares	0	0	2,986	0	0
Bank borrowing	903	722	(300)	(500)	(500)
New loans from related parties	297	12	0	0	0
Other financing activities	(889)	(1,747)	(242)	(316)	(356)
Net cash from financing activities	**311**	**(1,013)**	**2,443**	**(816)**	**(856)**
Net change in cash	615	(833)	3,229	80	387
Cash at the beginning of the year	573	1,188	355	3,584	3,663
Cash at the end of the year	**1,188**	**355**	**3,584**	**3,663**	**4,050**

Balance sheet

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Non-current assets	**2,673**	**3,869**	**3,911**	**3,948**	**3,981**
Plant and equipment	1,375	1,870	1,930	1,985	2,036
Goodwill	142	142	142	142	142
Intangible assets	49	34	24	14	4
Prepayments and deposits	22	325	325	325	325
Financial assets at FV through profit	860	902	902	902	902
Others	224	596	588	580	572
Current assets	**3,666**	**2,898**	**5,798**	**6,394**	**7,250**
Inventories	234	248	222	307	388
Accounts and other receivables	1,032	1,456	1,154	1,586	1,974
Amounts due from related parties	678	0	0	0	0
Bank balances and cash	1,188	355	3,584	3,663	4,050
Others	534	838	838	838	838
Current liabilities	**4,111**	**3,429**	**2,838**	**2,552**	**2,278**
Accounts and other payables	1,815	1,673	1,382	1,596	1,822
Bank Loans & Lease liabilities	1,993	1,670	1,370	870	370
Amounts due to related parties	204	0	0	0	0
Tax payables	100	86	86	86	86
Non-current liabilities	**662**	**1,858**	**1,858**	**1,858**	**1,858**
Deferred income	331	471	471	471	471
Deferred tax liabilities	208	117	117	117	117
Total net assets	**1,565**	**1,480**	**5,013**	**5,933**	**7,095**
Minority interest	0	0	0	0	0
Shareholders' equity	**1,565**	**1,480**	**5,013**	**5,933**	**7,095**

Key ratios

YE 31 Dec	FY18A	FY19A	FY20E	FY21E	FY22E
Sales mix (%)					
Sales of pharmaceutical	95.5	95.3	94.7	96.1	96.8
Promotion service income	4.5	4.7	5.3	3.9	3.2
Total	100	100	100	100	100
Profit & loss ratios (%)					
Gross margin	83	82	82	83	83
EBITDA margin	23	26	22	23	23
Pre-tax margin	21	21	17	20	21
Net margin	16	20	15	18	18
Effective tax rate	21	7	13	13	14
Balance sheet ratios					
Current ratio (x)	0.9	0.8	2.0	2.5	3.2
Trade receivables turnover days	67	83	83	83	83
Trade payables turnover days	124	116	116	116	116
Net debt to equity ratio (%)	56	155	Net cash	Net cash	Net cash
Returns (%)					
ROE	46.9	67.8	13.6	19.4	20.5
ROA	11.6	14.8	7.0	11.1	12.9

Source: Company data, CMBIS estimates

Valuation

Initiate at BUY with TP of HK$13.84

We expect Simcere's attributable net profit to grow from RMB1,004mn in 2019 to RMB1,453mn in 2022E, representing a CAGR of 13.1%. To factor in the potential contribution from innovative drug pipelines, we use DCF model in valuing the Company. We derive our target price of HK$13.84 based on a 10-year DCF valuation (WACC: 10.4%, terminal growth rate: 2.0%).

Figure 30: Risk-adjusted DCF valuation (terminal growth rate: 2.0%)

DCF Valuation (in Rmb mn)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	1,348	1,690	1,963	2,450	3,016	3,317	3,616	3,905	4,178	4,429
Tax rate	13.0%	14.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
EBIT*(1-tax rate)	1,173	1,454	1,669	2,082	2,563	2,820	3,073	3,319	3,552	3,765
+ D&A	155	159	163	162	162	179	195	210	225	238
- Change in working capital	(303)	(243)	(69)	(94)	(103)	(113)	(124)	(134)	(143)	(151)
- Capex	(200)	(200)	(150)	(150)	(150)	(150)	(150)	(150)	(150)	(150)
FCFF	**824**	**1,170**	**1,613**	**2,001**	**2,472**	**2,735**	**2,994**	**3,246**	**3,484**	**3,702**
Terminal value										**45,083**

Terminal growth rate	**2.0%**
WACC	**10.4%**
Cost of Equity	13.0%
Cost of Debt	5.0%
Equity Beta	1.0
Risk Free Rate	3.0%
Market Risk Premium	10.0%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%
Terminal value	16,800
Total PV	29,862
Net debt	(1,813)
Minority interest	0
Equity value （RMB mn)	31,675
Equity value （HK$ mn)	**36,101**
DCF per share (HK$)	**13.84**

Source: CMBIS estimates

Figure 31: Sensitivity analysis

		WACC				
		9.4%	**9.9%**	**10.4%**	**10.9%**	**11.4%**
Terminal growth rate	**3.0%**	17.48	16.10	14.92	13.88	12.98
	2.5%	16.66	15.42	14.34	13.40	12.56
	2.0%	15.95	14.82	**13.84**	12.97	12.20
	1.5%	15.32	14.30	13.39	12.59	11.86
	1.0%	14.78	13.83	12.99	12.24	11.57

Source: CMBIS estimates

Investment risks

If the Company's products are excluded or removed from national, provincial or other government-sponsored medical insurance programs, or are included in any national or provincial negative catalogs, Simcere's sales, profitability and business prospects could be materially and adversely affected.

The selection of pharmaceutical products for listing in medical insurance catalogues is based on a variety of factors, including clinical needs, frequency of use, effectiveness, safety and price, many of which are outside of any companies' control. Moreover, the relevant PRC government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that are already listed in any medical insurance catalogue. There can be no assurance that any of Simcere'sr products currently listed in these medical insurance catalogues will remain listed, or that changes in the scope of reimbursement will not negatively affect its products.

The prices of certain of Simcere's products are subject to pricing regulation, competition and other factors and therefore may decrease, which could materially and adversely affect Company's profitability.

It is typical in China that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, the centralized tender process, pricing regulation by the government, or increased competition from substitute products, including due to price adjustments by pharmaceutical companies (producers of the originator brands), whether or not voluntarily or as a result of government regulations or policies. The importation of competing products from countries where government price controls or other market dynamics result in lower prices may also exert downward pressure on the prices of Simcere's products.

Development of new products, in particular innovative drugs, is time-consuming and costly and the outcome is uncertain. Failure to develop and commercialize new products may affect Simcere's business prospects adversely.

The Company's long-term competitiveness depends on its ability to enhance existing products, diversify product offering and develop and commercialize new products through research and development activities. The development process of pharmaceutical products, in particular innovative drugs, is time-consuming and costly, and there can be no assurance that the Company's research and development activities will enable it to successfully develop new products. Simcere's research and development expenses accounted for 5.5%, 9.9% and 14.2% of its revenue in 2017, 2018 and 2019, respectively.

Appendix: Company Profile

Figure 32: Directors and management profile

Name	Age	Date of Joining	Date of Appointment	Position	Roles and Responsibilities
Mr. REN Jinsheng (任晋生)	57	Mar 1995	19 Nov 2019	CEO, Executive Director and Chairman of the Board	Responsible for the overall corporate business strategies, business operation and making significant business and operational decisions of the Company
MR. ZHANG Cheng (张诚)	46	Aug 2019	19 Nov 2019	COO and Executive Director	Responsible for the overall management of sales marketing business of the Company and the IT department of the Company
MR.WAN Yushan (万玉山)	49	May 2000	19 Nov 2019	CFO and Executive Director	Responsible for overseeing the financial and legal management and formulating financial strategies of the Company
Mr. TAN Renhong (唐任宏)	40	May 2019	19 Nov 2019	Senior Vice President and Executive Director	Responsible for the overall management of Shanghai R&D center and management of the pre-clinical R&D of Innovative pharmaceuticals of the Company
Mr. WANG Pin (王品)	45	Sep 2019	19 Nov 2019	Chief Science Officer	Responsible for the R&D of cell therapy business of the Company and the management of Boston R&D center
Mr. WANG Peng (王鹏)	60	Jul 2019	19 Nov 2019	Senior Vice President	Responsible for the innovative Pharmaceuticals R&D of CNS disease of the Company and the management of the national key laboratory
Mr. CHENG Xianghua (程向华)	43	Jun 2000	19 Nov 2019	Vice president	Responsible for the management of human resources, staff training and procurement of the Company
Mr. QIAN Haibo (钱海波)	57	Nov 1994	19 Nov 2019	Vice president	Responsible for the Investment Business Department and generic pharmaceutical projects initiation of the Company and business development in Hong Kong of the Company

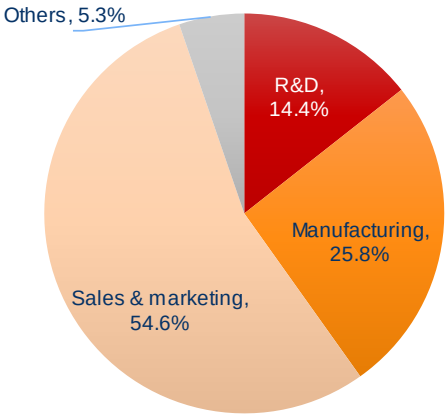
Source: Company data

Figure 33: Employee structure (as of 30 Jun 2020)

Function	# of employees	% of Total
Research & Development	756	14.4%
Manufacturing	1,354	25.8%
Sales & marketing	2,868	54.6%
Others (including. Operational and management)	277	5.3%
Total	5,255	100%

Source: Company data

Figure 34: Staff No. breakdown (as of 30 Jun 2020)



Source: Company data

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