亚盛医药 Ascentage Pharma (6855 HK)

lisaftoclax 展示出克服维奈克拉耐药的潜力，多项研究亮相 EHA 年会

Lisaftoclax demonstrated potential to overcome resistance to venetoclax

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK$72.30
目标价	HK$84.60
HTI ESG	5.0-4.4-5.0

E-S-G: 0-5, (Please refer to the Appendix for ESG comments)

市值	HK$25.19bn / US$3.21bn
日交易额 (3 个月均值)	US$29.18mn
发行股票数目	348.48mn
自由流通股 (%)	71%
1 年股价最高最低值	HK$72.30-HK$24.80

注：现价 HK$72.30 为 2025 年 06 月 23 日收盘价

资料来源：Factset

	1mth	3mth	12mth
绝对值	63.4%	88.0%	188.6%
绝对值（美元）	62.9%	86.2%	186.9%
相对 MSCI China	64.9%	91.6%	163.8%

Rmb mn	Dec-24A	Dec-25E	Dec-26E	Dec-27E
Revenue	981	569	2,992	2,801
Revenue (+/-)	342%	-42%	426%	-6%
Net profit	-456	-838	1,248	905
Net profit (+/-)	n.m.	n.m.	n.m.	-27%
Diluted EPS (Rmb)	-1.51	-2.77	4.13	3.00
GPM	97.0%	90.1%	98.1%	97.2%
ROE	-264.8%	-304.2%	138.6%	45.8%
P/E	n.m.	n.m.	17	24

资料来源：公司信息, HTI

(Please see APPENDIX 1 for English summary)

事件

Lisaftoclax 治疗髓系恶性肿瘤数据亮相 ASCO 年会：公司宣布在第 61 届美国临床肿瘤学会（ASCO）年会上，口头报告了在研 Bcl-2 抑制剂 APG-2575（lisaftoclax）联合去甲基化药物阿扎胞苷治疗治疗初治（TN）或既往接受过维奈克拉治疗的髓系恶性肿瘤（AML）患者的 Ib/II 期临床研究最新数据。Lisaftoclax 此次口头报告研究为一项全球多中心的 Ib/II 期研究（NCT04964518），截至 2025 年 4 月，共入组澳洲、美国 103 例患者，其中包括新诊断和复发/难治的 AML 和 MDS 患者。

截至 2025 年 4 月，在 28 例既往维奈克拉耐药的复发/难治 AML/混合表型急性白血病（MPAL）患者中，疗效可评估的患者有 22 例，总反应率（ORR）为 31.8%（7/22），其中 22.8%的患者 CR/ CR 伴血细胞未完全恢复（Cri）；4.6% 的患者获部分缓解（PR）；4.6%的患者获形态学无白血病状态（MLFS）。获得治疗反应的患者既往均接受过包括维奈克拉在内的多线治疗，且大部分（71%，5/7）患者基线存在 TP53 突变并伴随复杂染色体核型。

在 6 例疗效可评估的新诊断（ND）AML/MPAL 患者中，ORR 为 83.3%，其中 33.3%的患者获 CR/CRi，50%的患者获 PR。在 44 例疗效可评估 R/R AML/MPAL 患者中，ORR 为 43.2%，其中 31.8%的患者获 CR/CRi，4.5%的患者获 PR，6.8%的患者获 MLFS。

在 15 例疗效可评估的 ND MDS/慢性粒单核细胞白血病（CMML）患者中，ORR 为 80%，其中 40%的患者获 CR，40%的患者获骨髓 CR（mCR）。22 例疗效可评估的 R/R MDS/CMML 患者中，ORR 为 50%，其中 27.3%的患者获 CR，18.2%的患者获 mCR，4.5%的患者获 PR。

安全性数据：Lisaftoclax 联合 AZA 治疗，耐受性良好，安全性可控，常见不良反应主要体现在血液学事件，非血液学毒性不常见。绝大多数不良事件都可控制、可恢复、可耐受。

公司多项研究亮相 EHA：第 30 届欧洲血液学会年会（EHA 2025）于 2025 年 6 月 12 日-15 日在意大利米兰召开。公司宣布，原创 1 类新药奥雷巴替尼（耐立克®）和 EED 抑制剂 APG-5918 等品种的 13 项研究进展将在大会上公布。

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点评

lisaftoclax 展示出克服维奈克拉耐药的潜力。AML 的耐药机制复杂多样，而携带 TP53（p53 基因）突变的患者属于最难治疗的亚型之一，预后极差。针对该部分患者，传统化疗缓解率仅 15%-20%，mOS 约 6 个月；维奈克拉在 TP53 突变 AML 中疗效显著降低，III 期试验未改善生存。

2025 ASCO 首次报告了 lisaftoclax 在既往维奈克拉治疗失败的患者中的疗效和安全性数据，这也是国际上首次报告新型 Bcl-2 抑制剂克服维奈克拉耐药的临床研究。Lisaftoclax 在大多数患者（71%，5/7）中基线可见 TP53 突变且伴有复杂核型，仍展现出优异的临床疗效和良好的安全性，体现了 lisaftoclax 相较于海外同类药物的差异化优势。我们认为，该结果为后续开展该联合疗法用于此类患者的 III 期临床研究提供了有力的数据支持。

维奈克拉在 MDS 探索失败，lisaftoclax 有望后来居上。2025 ASCO 会议也披露了约 37 例 MDS/慢性粒单核细胞白血病（CMML，介于 MDS 和骨髓增生性肿瘤（MPN）之间）患者疗效。在 15 例疗效可评估的 ND MDS/慢性粒单核细胞白血病（CMML）患者中，ORR 为 80%，其中 40%的患者获 CR，40%的患者获骨髓 CR（mCR）。22 例疗效可评估的 R/R MDS/CMML 患者中，ORR 为 50%，其中 27.3%的患者获 CR，18.2%的患者获 mCR，4.5%的患者获 PR。我们认为数据初步展现了 lisaftoclax 在该适应症的疗效，有望填补相关难治领域临床的空白。

2025 年 6 月 16 日，罗氏/艾伯维宣布 Bcl-2 抑制剂维奈克拉+阿扎胞苷联合 1L 治疗高危骨髓增生异常综合征（HR-MDS）的 III 期临床 VERONA 没有达到 OS 主要终点，HR 为 0.908。目前尚未有 BCL-2 抑制剂在 MDS 适应症获批，公司的 lisaftoclax 在同靶点药物中进展最快，正在积极推进针对高危 MDS 患者（GLORA-4）以及 1L AML（GLORA-3）的全球注册临床研究，此次 ASCO 数据的读出增强了 lisaftoclax 的对外授权潜在预期。

EHA 大会数据更新，奥雷巴替尼治疗 Ph+ ALL 潜力明显：奥雷巴替尼在费城染色体阳性（Ph+）急性淋巴细胞白血病（ALL）领域展现出广阔的治疗前景：无论是在一线治疗新诊断 Ph+ ALL 患者，还是在复发/难治性患者及特定亚型（如伴有 FGFR1 重排的髓系/淋巴系肿瘤）研究中，均显示出较高的完全缓解（CR）率和完全分子学缓解（CMR）率，且整体耐受性良好。多项与其他药物（如维奈克拉联合阿扎胞苷、VP 方案、贝林妥欧单抗、奥加伊妥珠单抗等）的联合治疗研究也取得了积极成果，进一步表明奥雷巴替尼有潜力为 Ph+ ALL 患者带来更多治疗选择，并有望持续提升患者的长期生存获益。

估值

结合公司 ASCO 公布的数据，我们提高了 lisaftoclax 在 MDS 适应症的研发成功率，及全球潜在销售峰值。我们预计公司 FY25-27 营收分别为 5.7/29.9/28.0 亿元（不变）。对应 FY25-27 的净利润为-8.4/12.5/9.1 亿元（不变）。我们使用经风险调整的贴现现金流（DCF）模型及 2026-2033 财年的现金流预测对该公司进行估值。基于 WACC 10.0%，永续增长率 3.5%（原为 3.0%），对应目标价 84.6 HKD/股（前值：53.1 HKD/股），维持“优于大市”评级。

风险

药品销售未及预期的风险，新药研发风险，行业竞争加剧风险，汇率风险，政策风险等。

Table 1 DCF 估值模型

DCF Valuation (CNY mn)	2023	2024A	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Sales	**222**	**981**	**569**	**2,992**	**2,801**	**2,080**	**2,771**	**1,690**	**1,887**	**2,137**	**2,269**
y-y growth		341.8%	-42.0%	425.6%	-6.4%	-25.7%	33.2%	-39.0%	11.7%	13.2%	6.2%
Gross profit	**191**	**952**	**513**	**2,934**	**2,723**	**1,961**	**2,610**	**1,494**	**1,667**	**1,895**	**2,011**
y-y growth		397.1%	-46.1%	472.0%	-7.2%	-28.0%	33.0%	-42.8%	11.6%	13.7%	6.1%
EBIT		**(288)**	**(717)**	**1,383**	**1,047**	**524**	**1,375**	**568**	**1,390**	**2,257**	**2,931**
Tax rate		15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
EBIT*(1-tax rate)		**(245)**	**(609)**	**1,175**	**890**	**445**	**1,169**	**483**	**1,181**	**1,918**	**2,491**
+ D&A		82	56	57	58	59	60	61	62	63	64
- Change in working capital		92	(47)	(87)	44	(141)	67	(92)	(146)	136	(122)
- Capx		(92)	(72)	(74)	(75)	(77)	(78)	(79)	(81)	(82)	(84)
FCFF		**(163)**	**(673)**	**1,072**	**916**	**287**	**1,218**	**372**	**1,016**	**2,035**	**2,350**
Terminal value											37,185
FCF + Terminal value		(163)	(673)	1,072	916	287	1,218	372	1,016	2,035	39,535
Discount factor				0.95	0.86	0.79	0.71	0.65	0.59	0.54	0.49
PV of FCF + Terminal value		**-**	**-**	**1,019**	**792**	**225**	**870**	**241**	**599**	**1,090**	**19,248**

WACC	10.0%	**Terminal growth rate**	3.5%	Present value of enterprise (CNY mn)	24,085
Cost of Equity	11.7%			-Net debt (CNY mn)	(407)
Cost of Debt	4.0%			-MI (CNY mn)	(10)
Equity Beta	1.10			Equity value (CNY mn)	23,668
Risk Free Rate	1.8%			No. of shares	302
Market Risk Premium	9.0%			**DCF per share (CNY)**	**78.35**
Target Debt to Asset ratio	20%			CNY/HKD	1.08
Effective Corporate Tax Rate	15.0%			**DCF per share (HKD)**	**84.62**

资料来源：公司财报，HTI

表 2. 财务报表和盈利预测

Key financials	FY2024A	FY2025F	FY2026F	FY2027F
Revenue (CNY mn)	981	569	2,992	2,801
Operating Profit /Loss (CNY mn)	(288)	(717)	1,383	1,047
Pre-tax profit / Loss (CNY mn)	(446)	(844)	1,258	913
Net income to ord equity (CNY mn)	(456)	(838)	1,248	905
Revenue growth	341.8%	-42.0%	425.6%	-6.4%
Net profit growth	-50.7%	83.5%	-249.0%	-27.5%
ROE	-264.8%	-304.2%	138.6%	45.8%

Balance Sheet (CMY mm)	FY2024A	FY2025F	FY2026F	FY2027F
Total cash and equivalents	1,261	1,362	2,581	3,592
Inventories	7	39	7	55
Account and other receivables	83	222	67	304
Trade receivables	N.A.	N.A.	N.A.	N.A.
Other current assets	123	92	94	96
Total current assets	**1,474**	**1,715**	**2,749**	**4,046**
Property, plant and equipment	849	862	875	888
Other non-current assets	294	273	282	292
Total non-current assets	**1,144**	**1,135**	**1,157**	**1,180**
Total assets	**2,618**	**2,850**	**3,906**	**5,226**
Contract liabilities	37	38	39	40
Trade and other payable	258	263	269	274
Bank borrowing	779	826	875	928
Other current liabilities	92	216	(57)	272
Total current liabilities	**1,167**	**1,344**	**1,126**	**1,513**
Bank borrowing	248	263	279	296
Contract liabilities	N.A.	N.A.	N.A.	N.A.
Other liabilities	929	966	977	987
Total non-current liabilities	**1,177**	**1,230**	**1,256**	**1,283**
Total liabilities	**2,344**	**2,573**	**2,381**	**2,796**
Shareholder's equity	**264**	**267**	**1,515**	**2,420**
Minority interests	10	10	10	10
Total equity	**274**	**277**	**1,525**	**2,430**
Total liabilities & shareholders' equity	**2,618**	**2,850**	**3,906**	**5,226**

Cash flow (CNY mn)	FY2024A	FY2025F	FY2026F	FY2027F
Operating profit	**(288)**	**(717)**	**1,383**	**1,047**
Deprecation and amortisation	(82)	(56)	(57)	(58)
Changes in working capital	(47)	(87)	44	(141)
Other operating cash flow	306	154	(21)	297
Cash generated from operations	**(111)**	**(706)**	**1,349**	**1,145**
Capex	(76)	(71)	(72)	(73)
Other investing cash flow	(286)	15	15	16
Net cash flow from investing activities	**(362)**	**(56)**	**(57)**	**(57)**
Change in borrowings	(127)	56	59	62
Proceeds from changes in capital	#REF!	840	-	-
Other financing cash flow	#REF!	(124)	(131)	(139)
Net cash flow from financing activities	**315**	**772**	**(73)**	**(78)**
Cash at beginning of period	1,038	879	889	2,109
Net change in cash	**(159)**	**10**	**1,219**	**1,011**
Forex effects	-	-	-	-
Implied cash at end of period	**879**	**889**	**2,109**	**3,119**
Free cash flow	**(188)**	**(777)**	**1,277**	**1,072**

Profit & Loss (CNY mn)	FY2024A	FY2025F	FY2026F	FY2027F
Total turnover	981	569	2,992	2,801
Cost of sales	(29)	(56)	(58)	(78)
Gross profit	952	513	2,934	2,723
Total operating costs	(1,240)	(1,230)	(1,551)	(1,676)
Operating profit	(288)	(717)	1,383	1,047
Operating EBITDA	(370)	(773)	1,326	989
Depreciation and amortisation	(82)	(56)	(57)	(58)
Operating EBIT	(288)	(717)	1,383	1,047
Interest income (expense)	(64)	(124)	(131)	(139)
Pre-tax profit	(446)	(844)	1,258	913
Taxation	(10)	7	(10)	(7)
Net Income	(456)	(838)	1,248	905
Minorities	(0)	(0)	0	0
Net Income to ord equity	(456)	(838)	1,248	905
One-off expense	N.A.	N.A.	N.A.	N.A.
Normalized net income	**N.A.**	**N.A.**	**N.A.**	**N.A.**

Per Share Data	FY2024A	FY2025F	FY2026F	FY2027F
EPS (CNY)	(1.5)	(2.8)	4.1	3.0
Revenue per share (CNY)	3.2	1.9	9.9	9.3
Operating EBITDA per share (CNY)	(1.2)	(2.6)	4.4	3.3
BVPS (CNY)	0.9	0.9	5.0	8.0
DPS (CNY)	N.A.	N.A.	N.A.	N.A.
Recurrent cash flow per share (CNY)	(0.5)	0.0	4.0	3.3
Shares in issue (million)	302	302	302	302
Year end adjusted shares in issue (million)	N.A.	N.A.	N.A.	N.A.

Key Ratios	FY2024A	FY2025F	FY2026F	FY2027F
Growth				
Revenue growth	341.8%	-42.0%	425.6%	-6.4%
Operating profit growth	-65.4%	148.9%	-292.9%	-24.3%
Net profit growth	-50.7%	83.5%	-249.0%	-27.5%
Margins				
Gross margin	97.0%	90.1%	98.1%	97.2%
Operating EBITDA margin	-37.7%	-135.8%	44.3%	35.3%
Operating margin	-29.4%	-125.9%	46.2%	37.4%
Pretax profit margin	-45.5%	-148.3%	42.1%	32.6%
Tax rate	-0.8%	-0.8%	-0.8%	-0.8%
Net profit margin	-46.6%	-147.1%	41.7%	32.3%
Key Ratios				
ROE	-264.8%	-304.2%	138.6%	45.8%
ROA	-17.8%	-30.6%	37.0%	19.8%
Capex/revenue	-7.8%	-12.4%	-2.4%	-2.6%
Current ratio (x)	1.3	1.3	2.4	2.7
Creditor days	800.0	1000.0	500.0	500.0
Debtor days	110.0	105.0	100.0	95.0
Inventory days	146.0	145.0	160.0	158.0
Sales/avg assets	0.4	0.2	0.9	0.6
Credit analysis				
Debt/EBITDA (x)	-2.8	-1.4	0.9	1.2
Debt/equity	375%	394%	76%	50%
Net debt to equity	-85%	-99%	-94%	-97%

资料来源：公司年报，HTI

APPENDIX 1

Summary

Event

Lisaftoclax Data for Myeloid Malignancies Presented at ASCO Annual Meeting: At the 61st American Society of Clinical Oncology (ASCO) Annual Meeting, Ascentage Pharma presented new clinical data on lisaftoclax (APG-2575), its investigational Bcl-2 inhibitor, in combination with azacitidine (AZA) for the treatment of myeloid malignancies. The results were shared via an oral presentation, highlighting findings from a global Phase Ib/II multicenter study (NCT04964518) involving treatment-naïve (TN) and venetoclax-pretreated patients diagnosed with acute myeloid leukemia (AML) or other myeloid malignancies. As of April 2025, a total of 103 patients had been enrolled across sites in Australia and the United States, including newly diagnosed and relapsed/refractory (R/R) patients with AML and myelodysplastic syndromes (MDS).

Among 28 relapsed/refractory AML or mixed phenotype acute leukemia (MPAL) patients with prior venetoclax resistance, 22 were evaluable for efficacy. The overall response rate (ORR) in this group was 31.8%, with 22.8% achieving complete remission (CR) or CR with incomplete hematologic recovery (CRi), 4.6% achieving partial response (PR), and another 4.6% reaching morphologic leukemia-free state (MLFS). Notably, all responders had received multiple prior lines of therapy including venetoclax, and most (71%, 5 out of 7) carried TP53 mutations and complex cytogenetic profiles.

For newly diagnosed AML/MPAL patients, six were evaluable, with an impressive ORR of 83.3%. Among them, 33.3% achieved CR/CRi, and 50% achieved PR. Among 44 evaluable patients with R/R AML/MPAL, the ORR was 43.2%, with 31.8% achieving CR/CRi, 4.5% PR, and 6.8% MLFS.

In patients with newly diagnosed MDS or chronic myelomonocytic leukemia (CMML), 15 were evaluable. The ORR in this group was 80%, with 40% achieving CR and 40% marrow CR (mCR). Among 22 evaluable R/R MDS/CMML patients, the ORR was 50%, including 27.3% CR, 18.2% mCR, and 4.5% PR.

Safety data: Lisaftoclax in combination with azacitidine was well tolerated with manageable safety. The most common adverse events were hematologic in nature, while non-hematologic toxicities were infrequent. Most adverse events were controllable, reversible, and tolerable.

Multiple Studies Presented at EHA: The 30th European Hematology Association (EHA) Annual Congress (EHA 2025) was held in Milan, Italy, from June 12 to 15, 2025. The company announced that 13 research updates on its innovative Class 1 new drug olverembatinib and EED inhibitor APG-5918, among others, would be presented at the conference.

Comments

Lisaftoclax Shows Potential in Overcoming Venetoclax Resistance. Resistance mechanisms in AML are complex and varied, with TP53-mutated patients representing one of the most difficult subtypes to treat and having a particularly poor prognosis. For these patients, traditional chemotherapy achieves a remission rate of only 15%–20%, with a median overall survival (mOS) of approximately 6 months. Venetoclax demonstrates significantly reduced efficacy in TP53-mutated AML, and Phase III trials have failed to show a survival benefit.

At ASCO 2025, the efficacy and safety data of lisaftoclax in patients who had previously failed venetoclax treatment were reported for the first time. This marked the first international clinical study demonstrating a novel Bcl-2 inhibitor overcoming venetoclax resistance. Notably, lisaftoclax showed promising clinical efficacy and good safety in the majority of patients (71%, 5 out of 7) who had TP53 mutations at baseline along with complex karyotypes. This highlights lisaftoclax's differentiated advantages compared to similar drugs overseas.

We think these results provide strong data support for advancing to a Phase III clinical trial of this combination therapy in such high-risk patient populations.

Venetoclax Falls Short in MDS; Lisaftoclax Poised to Take the Lead. At the 2025 ASCO Meeting, data were disclosed on approximately 37 patients with myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML), a condition that lies between MDS and myeloproliferative neoplasms (MPN). Among 15 evaluable treatment-naïve (ND) MDS/CMML patients, the overall response rate (ORR) was 80%, with 40% achieving complete remission (CR) and another 40% achieving marrow CR (mCR). In 22 evaluable relapsed/refractory (R/R) MDS/CMML patients, the ORR was 50%, including 27.3% with CR, 18.2% with mCR, and 4.5% with partial remission (PR). We think this data provides preliminary evidence of lisaftoclax's efficacy in this indication and suggests its potential to address an unmet clinical need in this difficult-to-treat population.

On June 16, 2025, Roche/AbbVie announced that the Phase III VERONA trial evaluating venetoclax combined with azacitidine as a first-line treatment for high-risk MDS (HR-MDS) failed to meet its primary endpoint of overall survival (OS), with a hazard ratio (HR) of 0.908. Currently, no BCL-2 inhibitor has been approved for the MDS indication. Lisaftoclax, among drugs targeting the same pathway, is the most advanced in clinical development. It is actively progressing in global registration studies for high-risk MDS (GLORA-4) and first-line AML (GLORA-3). The latest ASCO data further strengthens lisaftoclax's out-licensing potential.

EHA Data Update Highlights Olverembatinib's Strong Potential in Treating Ph+ ALL. Olverembatinib continues to demonstrate promising therapeutic potential in Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL). It has shown high complete remission (CR) and complete molecular remission (CMR) rates in both frontline treatment of newly diagnosed Ph+ ALL patients and in relapsed/refractory cases, as well as in specific subtypes such as myeloid/lymphoid neoplasms with FGFR1 rearrangements. Overall tolerability has also been favorable.

Multiple combination therapy studies—including those with venetoclax plus azacitidine, VP regimens, blinatumomab, and inotuzumab ozogamicin—have reported encouraging results. These findings further support olverembatinib's potential to expand treatment options for Ph+ ALL patients and to continuously improve long-term survival outcomes.

Valuation

Following the data presented at ASCO, we have increased our estimated probability of success for lisaftoclax in the MDS indication, as well as its projected global peak sales. Our revenue forecasts for FY25–27 remain unchanged at RMB 570 million / 2.99 billion / 2.80 billion, respectively. Corresponding net profit estimates for FY25–27 are also maintained at RMB -840 million / 1.25 billion / 910 million.

We continue to value the company using a risk-adjusted discounted cash flow (DCF) model, based on projected cash flows from FY2026 to FY2033. Using a WACC of 10.0% and a terminal growth rate of 3.5%, we raise our target price to HKD 84.6 per share (previously HKD 53.1 per share) and reiterate our "Outperform" rating.

Risks

New drug development risk, regulatory approval risk, and commercialization underperformance risk.

APPENDIX 2

ESG Comments

Environmental:

overall good

Social:

overall good

Governance:

overall good

附录 APPENDIX

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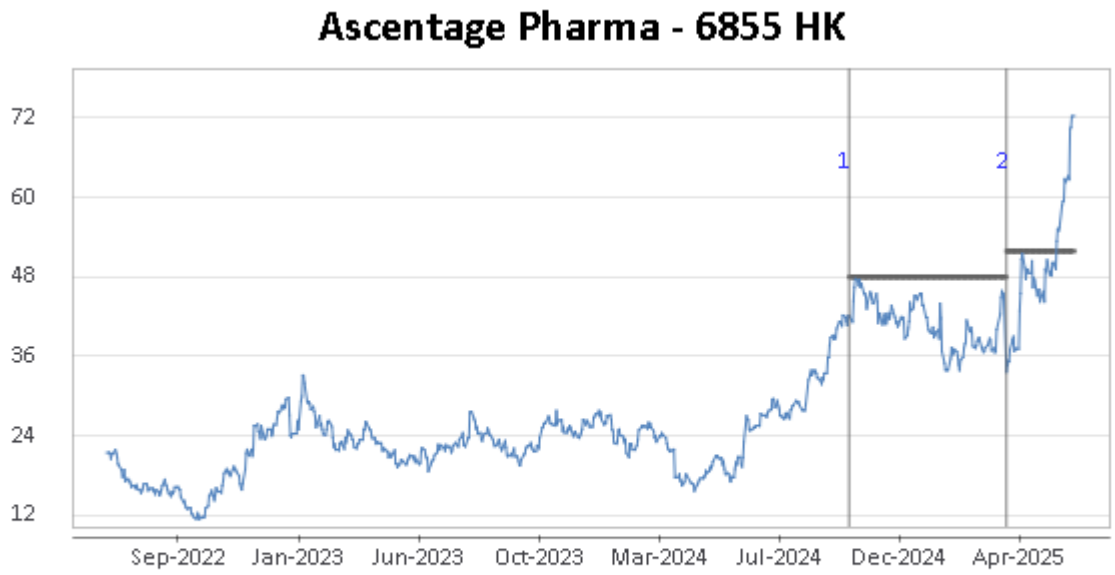

1. 11 Oct 2024 OUTPERFORM at 40.70 target 48.00.
2. 7 Apr 2025 OUTPERFORM at 44.85 target 51.90.

Source: Company data Bloomberg, HTI estimates