Henlius Biotech (2696 HK)

Large potential in innovative pipelines

- **HLX43, a global leading PD-L1 ADC targeting broad indications**. As one of the most advanced PD-L1 ADCs globally, HLX43 has demonstrated encouraging and competitive early efficacy in clinical trials for IO-resistant NSCLC patients. Among heavily pre-treated patients (median of three prior lines), HLX43 2mg/kg monotherapy achieved an ORR of 38.1% and an mPFS of 5.4 months. Notably, HLX43 showed consistent anti-tumor activity across both squamous and non-squamous NSCLC subtypes (cORR of 33.3% in each), regardless of PD-L1 expression status or the presence of brain/liver metastases. In terms of safety, HLX43 was well tolerated with low hematologic toxicity, supporting its potential for future development in first-line settings and in combination regimens. HLX43 is currently undergoing multiple Ph2 trials across broad indications of NSCLC, HCC, ESCC, NPC, HNSCC, and others. We also see the potential of HLX43 in combo with serplulimab (PD-1) likely in front-line. HLX43 demonstrates promising potential for out-licensing opportunities.
- **HLX22 is another potential blockbuster.** We view HLX22 (HER2 mAb) to be a strong alternative for 1L HER2+ gastric cancer (GC). In a Ph2 trial, with a median follow-up of 20.3 months, HLX22 (15 mg/kg) + trastuzumab + chemo showed dramatically improved efficacy over the current standard of care (trastuzumab + chemo), with median PFS not reached vs 8.2 months in the control arm. The hazard ratio was 0.20 (0.06–0.45), representing an 80% reduction in the risk of disease progression. Henlius is advancing a global Ph3 MRCT in this indication.
- **Serplulimab shows promising potential in MSS CRC**. Serplulimab (PD-1) represents a compelling opportunity in first-line MSS colorectal cancer—a large and underserved population. In a Ph2 trial, serplulimab + chemo + bevacizumab demonstrated numerically longer PFS (16.8 vs 10.1 months; HR 0.66) and OS (23.5 vs 20.2 months; HR 0.79) vs chemo + bevacizumab, which suggests meaningful clinical benefits in this difficult-to-treat setting. A Ph3 trial of serplulimab is ongoing in China and other Asian markets.
- **To capture global biosimilar opportunities through extensive partnerships**. Backed by strong commercial performance of HANQUYOU (trastuzumab) and serplulimab, Henlius has transitioned into a profit-generating company. Leveraging its broad and growing network of global partnerships, Henlius is actively expanding its presence in the international biosimilar market. Notably, marketing authorization applications for HLX14 (denosumab) and HLX11 (pertuzumab) are currently under FDA review, positioning the company to unlock significant overseas revenue streams upon approval and launch. In addition, Henlius is advancing multiple biosimilar assets in development, offering further licensing potential.
- **Maintain BUY.** We see potential of Henlius to evolve from a profitable bio-similar-focused company into a leading innovator in biologics. We revise our TP to HK$61.98 (WACC 9.83%, terminal growth 3.0%) from HK$20.33, a TP we previously derived before Henlius' potential privatization last year.

Earnings Summary

(YE 31 Dec)	FY23A	FY24A	FY25E	FY26E	FY27E
Revenue (RMB mn)	5,395	5,724	6,581	4,763	5,441
YoY growth (%)	67.8	6.1	15.0	(27.6)	14.2
Net profit (RMB mn)	546.0	820.5	1,244.3	585.2	836.4
YoY growth (%)	na	50.3	51.7	(53.0)	42.9
EPS (Reported) (RMB)	1.01	1.51	2.29	1.08	1.54
P/E (x)	45.2	30.1	19.8	42.2	29.5
R&D expenses (RMB mn)	(1,119)	(1,035)	(1,100)	(770)	(847)
Admin expenses (RMB mn)	(384)	(371)	(392)	(290)	(334)
CAPEX (RMB mn)	(474)	(164)	(150)	(150)	(150)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	**HK$61.98**
(Previous TP	HK$20.33)
Up/Downside	**25.0%**
Current Price	**HK$49.60**

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Stock Data

Mkt Cap (HK$ mn)	26,957.3
Avg 3 mths t/o (HK$ mn)	54.8
52w High/Low (HK$)	49.60/15.74
Total Issued Shares (mn)	543.5

Source: FactSet

Shareholding Structure

Fosun	48.9%
Henlius Biopharma	8.1%

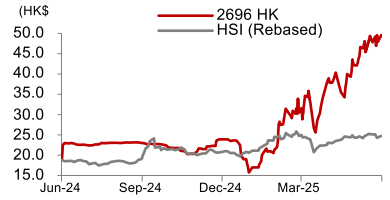
Source: HKEx

Share Performance

	Absolute	Relative
1-mth	17.8%	15.8%
3-mth	62.6%	62.6%
6-mth	107.5%	74.2%

Source: FactSet

12-mth Price Performance



Source: FactSet

Content

HLX43, a global leading PD-L1 ADC targeting broad indications

As one of the most advanced PD-L1-targeting ADCs in global development, HLX43 demonstrates strong potential to be best-in-class, offering enhanced potency and tolerability. It is engineered using MediLink's proprietary tumor microenvironment-activatable linker-payload platform (TMALIN), enabling selective toxin release within the tumor microenvironment.

PD-L1 is broadly expressed across tumor types, while showing limited expression in normal tissues - making it an ideal target for ADCs. In ADCs, PD-L1 serves a dual role as both an immune checkpoint inhibitor and a tumor-associated antigen (TAA), providing a unique mechanism of action for PD-L1 ADCs — targeted toxin delivery and reversal of immune suppression. This dual-function approach allows PD-L1 ADCs to target a wide range of tumor types, potentially independent of PD-L1 expression levels. HLX43 is currently undergoing multiple Ph2 proof-of-concept trials across various tumor indications, including NSCLC, HCC, ESCC, NPC, HNSCC, etc. In addition, we see strong potential for HLX43 in combination with PD-1 monoclonal antibodies (e.g., serplulimab), further expanding its therapeutic applicability across broader patient populations, potentially in front-line upon clinical verification.

Differentiated design to offer enhanced potency and tolerance

PD-(L)1 monoclonal antibodies have transformed cancer treatment across multiple lines of therapy. However, many patients who fail to respond or develop resistance to PD-(L)1 therapy face limited options, underscoring significant unmet medical needs.

HLX43 is a novel ADC developed by Henlius in collaboration with MediLink Therapeutics. Based on MediLink's TMALIN payload-linker technology, HLX43 targets PD-L1 using an engineered humanized IgG1 monoclonal antibody linked to a camptothecin-based topoisomerase I inhibitor via a tripeptide linker. HLX43 exerts its anti-tumor effects through two complementary mechanisms: (1) precise binding to PD-L1-positive tumor cells, followed by internalization and intracellular release of the cytotoxic payload, and (2) selective cleavage of the linker in the tumor microenvironment (TME) without needing internalisation of the ADC, thereby delivering the toxin into PD-L1-expressing malignant cells, while sparing the normal cells. In addition, HLX43 induces bystander killing effects, thereby further decreasing PD-L1-expessing tumor cells.

Unlike SGN-PDL1V (PDL1V, PD-L1 ADC developed by Pfizer/Seagen), which uses the traditional MMAE linker-payload with an anti-mitotic agent, HLX43 employs a tumor microenvironment activable tripeptide linker and a novel topoisomerase-I inhibitor payload, C24. This next-generation design offers several advantages, including superior stability, enhanced tumor-killing effects, and a stronger bystander effect. For instance, in Ph1 clinical trials, HLX43 delivered 37.5% ORR for CPS ≥1 IO-resistant NSCLC patients who has a median 3.0 lines of prior treatment, which were better than PDL1V's 32.0% ORR for patients with slightly better baseline (median 2.0 lines of prior lines of therapy), showing the stronger efficacy of HLX43.

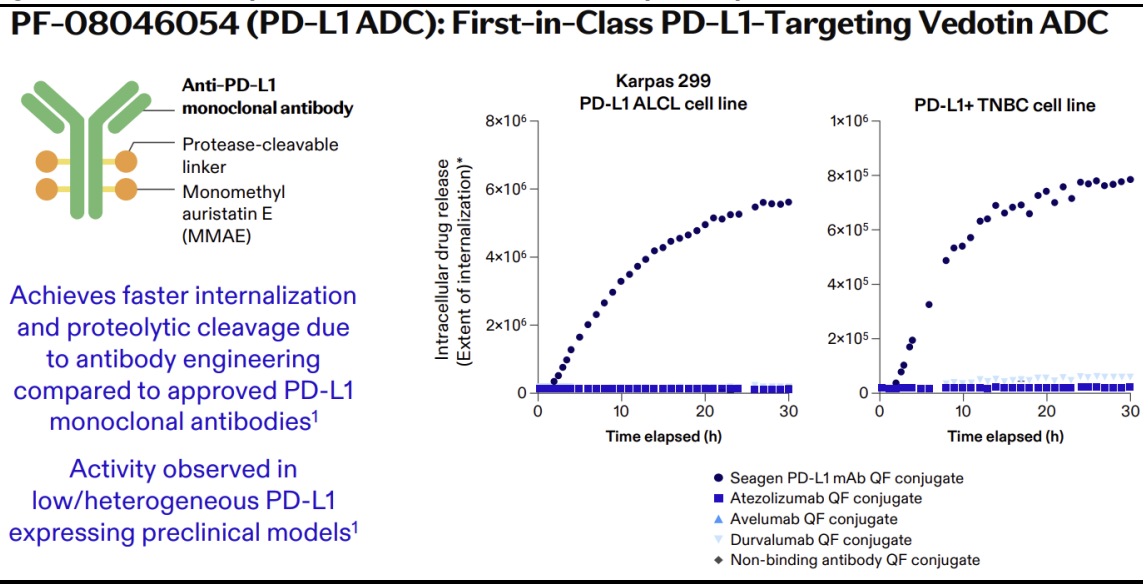
Topoisomerase-I inhibitors, as validated by Enhertu (T-DXd), are known for their potent anti-tumor activity, shorter half-life in the bloodstream, and improved safety profile. The TOP1i payload, C24, of HLX43 is 4-10 times more potent than DXd, together with a higher drug-to-antibody ratio (DAR) of 8 (compared with PDL1V's DAR of 4), could make HLX43 a more effective treatment option. Meanwhile, with C24's shorter half-life to enable rapid clearance from systemic circulation, we expect HLX43 to be able to avoid high systemic exposure to offer a favorable safety profile. Additionally, due to the tumor microenvironment activable feature besides the internalization, HLX43 could deliver a stronger bystander effect than PDL1V. HLX43 has shown remarkable efficacy in PD-L1 low-expression tumor models, such as hepatocellular carcinoma (HCC), potentially address a broader patient population compared to PDL1V.

Figure 1:Design of HLX43 vs SGN-PDL1V

	Henlius' HLX43	Pfizer's PF-08046054 (SGN-PDL1V, PDL1V)
Linker	TMALIN (Tumor Microenvironment Activable LINker from MediLink)	Protease-cleavable mc-vc (maleimidocaproyl-valine-citrulline) linker
Payload	TOP1i (C24, 4-10 times potent vs DXd, shorter half-life vs DXd)	MMAE
DAR (drug-to-antibody ratio)	8	4
Antibody engineering	HLX20, PD-L1 targeted hIgG1, similar internalization rate to SGN-PDL1V	Engineered for enhanced internalization (improved ADC uptake into tumor cells)
Mechanism of action	Combines PD-L1 blockade with DNA damage (via TOP1i), plus stronger bystander effect	Combines PD-L1 blockade with microtubule disruption (via MMAE)
Key advantages	Superior efficacy in PD-L1 low-expressing tumors (e.g., liver cancer); potent in PD-1 resistant tumors	Proven linker-payload stability
	Enhance safety profile (shorter TOP1i half-life in blood to be cleared rapidly)	Support PD-L1 signal blockade

Source: Pfizer, Henlius, CMBIGM

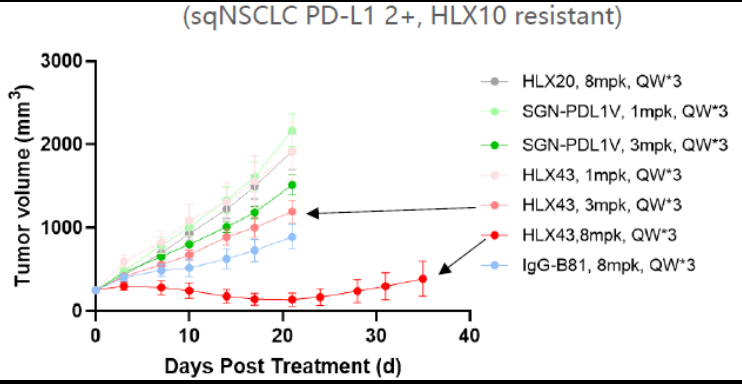
Figure 2:Pre-clinical profile of Pfizer's PF-08046054 (PDL1V)



Source: Pfizer R&D Slides (link), CMBIGM

As demonstrated in the preclinical study below, in a PD-1 resistant and PD-L1 positive sq-NSCLC mouse model, HLX43 demonstrated stronger anti-tumor activity than SGN-PDL1V at a dose of 3mg/kg QW×3. At 8mg/kg QW×3, HLX43 exhibited significant anti-tumor efficacy. HLX20 (the naked antibody component of HLX43) showed weaker effects at 8mg/kg compared to HLX43 (the ADC), indicating that the ADC design of HLX43—such as toxin conjugation—enhanced its therapeutic potency.

Figure 3: Strong potency of HLX43 vs SGN-PDL1V in PD-1 resistant, PD-L1 positive sqNSCLC mouse model



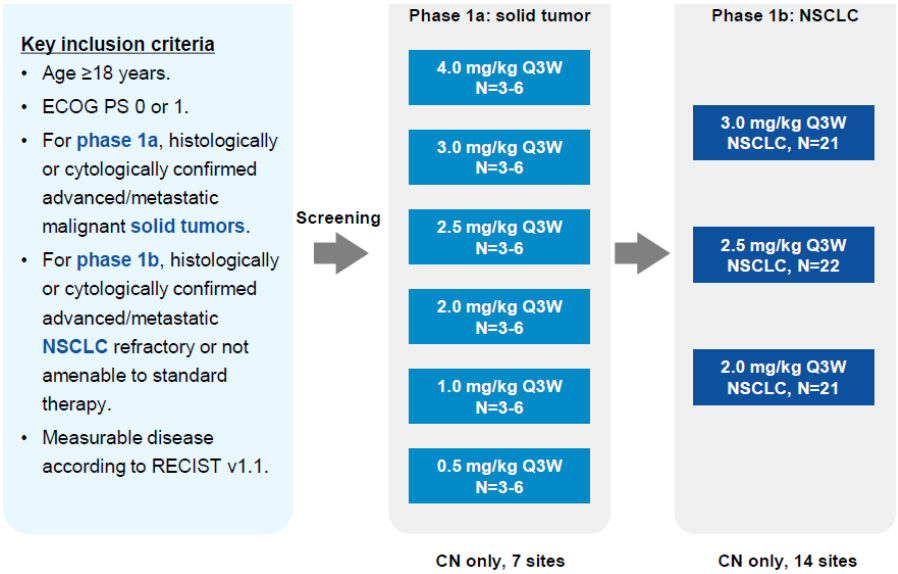
Source: Company data (Henlius R&D day) (link), CMBIGM. Notes: 1) HLX20, PD-L1 mAb developed by Henlius, which is the antibody of HLX43. 2) IgG-B81, control ADC.

Promising HLX43 Ph1 data released at 2025 ASCO

HLX43 has demonstrated encouraging and competitive early efficacy in clinical trials for NSCLC patients who were resistant to prior standard therapies. Among heavily pre-treated patients (median of three prior lines), HLX43 2mg/kg monotherapy achieved an ORR of 38.1% and an mPFS of 5.4 months. Notably, HLX43 showed consistent anti-tumor activity across both squamous and non-squamous NSCLC subtypes (cORR of 33.3% in each), regardless of PD-L1 expression status or the presence of brain/liver metastases. In terms of safety, HLX43 was well tolerated with low hematologic toxicity, supporting its potential for future development in first-line settings and in combination regimens, in our view.

The encouraging Ph1 clinical data of HLX43 in IO-resistant NSCLC was presented at 2025 ASCO Meeting (link). This Ph1 study consisted of 2 parts. Parts 1 and 2 were dose escalation and dose expansion phases, respectively, to explore different doses of HLX43. In Part 1, patients with advanced/metastatic malignant solid tumors refractory to or not amenable to standard therapies received intravenous HLX43 at 0.5 mg/kg, 1 mg/kg, 2 mg/kg, 3 mg/kg, or 4 mg/kg, Q3W. In Part 2, patients with advanced/metastatic NSCLC refractory to standard treatment received HLX43 at 2 mg/kg, 2.5 mg/kg, or 3 mg/kg, Q3W.

Figure 4: Study design of HLX43's Ph1 study



Source: Company data, CMBIGM

As of 28 Mar 2025, 21 patients (NSCLC, TSCC, SCLC, HNSCC, etc) were enrolled in Phase 1a to receive HLX43 at 0.5 mg/kg (n = 3), 1.0 mg/kg (n = 3), 2.0 mg/kg (n = 3), 2.5 mg/kg (n = 3), 3.0 mg/kg (n = 3), or 4.0 mg/kg (n = 6). In Phase 1b, 21 patients with NSCLC (15 squamous type, 6 nonsquamous type) were enrolled to receive HLX43 at 2.0 mg/kg, with the results reported at 2025 ASCO bellow, while enrolment of patients in the 2.5 and 3.0 mg/kg dose groups of the Phase 1b was ongoing.

Figure 5: Patient baseline characteristics of the HLX43's Ph1 study

n (%)	Phase 1a (n = 21)	Phase 1b 2.0 mg/kg (n = 21)
Median age (range), years	52 (34–71)	56 (39–73)
Male	13 (61.9)	14 (66.7)
ECOG PS		
0	11 (52.4)	5 (23.8)
1	10 (47.6)	16 (76.2)
Prior anti-cancer therapy		
Chemotherapy+immunotherapy	16 (76.2)	16 (76.2)
Chemotherapy	11 (52.4)	11 (52.4)
Target therapy	10 (47.6)	9 (42.9)
Immunotherapy	6 (28.6)	5 (23.8)
Prior lines of therapy		
1	6 (28.6)	7 (33.3)
2	8 (38.1)	1 (4.8)
3	3 (14.3)	6 (28.6)
≥ 4	4 (19.0)	7 (33.3)
Median (range)	2.0 (1–6)	3.0 (1–7)

n (%)	Phase 1b 2.0 mg/kg (n = 21)
NSCLC subtype	
Squamous	15 (71.4)
EGFR wild type	100%
Nonsquamous	6 (28.6)
EGFR wild type	100%
Used docetaxel	
Yes	9 (42.9)
No	12 (57.1)
Brain metastasis	
Yes	6 (28.6)
No	15 (71.4)
Liver metastasis	
Yes	3 (14.3)
No	18 (85.7)
PD-L1 expression level*	
CPS ≥ 1	16 (76.2)
CPS < 1	5 (23.8)

Source: Company data, CMBIGM

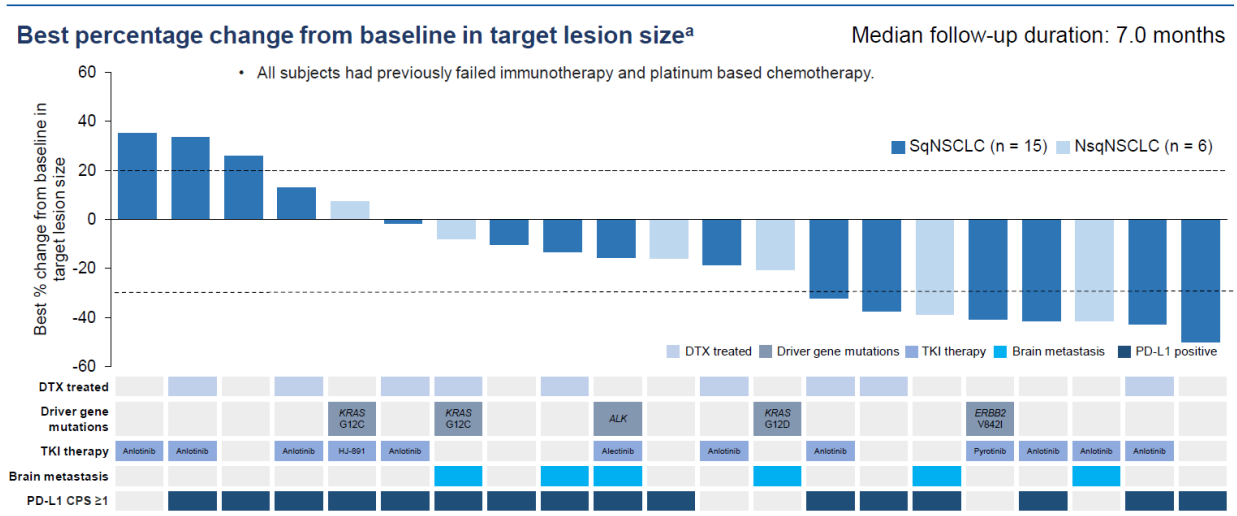
Investigator-assessed ORR for the Phase 1a cohorts was 36.8%, with 3/4 patients with thymic squamous cell carcinoma (ESCC) achieving partial response (ORR = 75%). For the Phase 1b 2.0 mg/kg cohort, investigator-assessed ORR was 38.1%, and ORR among the squamous and nonsquamous NSCLC patients were 40.0% (cORR 33.3%) and 33.3% (cORR 33.3%), respectively. With 7.0 months of median follow-up, the mPFS in the Phase 1b cohort reached 5.4 months, which was quite competitive considering that the enrolled NSCLC patients were heavily pre-treated and IO-resistant (median prior 3.0 lines of therapies) regardless of brain/liver metastasis and PD-L1 expressions.

Figure 6: Efficacy data of HLX43 Ph1b 2.0mg/kg

Median follow-up duration: 7.0 months

Tumor response per RECIST v1.1[a]	Phase 1b 2.0 mg/kg (n = 21)
CR, n (%)	0
PR, n (%)	8 (38.1)
SD, n (%)	9 (42.9)
PD, n (%)	4 (19.0)
NE, n (%)	0
ORR, % (95% CI)	38.1 (18.1–61.6)
Confirmed ORR, % (95% CI)	33.3 (14.6–57.0)
ORR in patients who had ≥3 prior lines of therapy, %	38.5 (5/13)
DCR, % (95% CI)	81.0 (58.1–94.6)
mDOR, months (95% CI)	NR (1.4–NE)
mPFS, months (95% CI)	5.4 (4.0–6.3)
mOS, months (95% CI)	NR (6.7–NE)

Subgroup analysis of tumor response per RECIST v1.1[a]	ORR % (95% CI)	DCR % (95% CI)
NSCLC subtype		
Squamous (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Confirmed response	33.3 (11.8–61.6)	73.3 (44.9–92.2)
Nonsquamous (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
Confirmed response	33.3 (4.3–77.7)	100 (54.1–100)
Used docetaxel		
Yes (n = 9)	33.3 (7.5–70.1)	77.8 (40.0–97.2)
No (n = 12)	41.7 (15.2–72.3)	83.3 (51.6–97.9)
Brain metastasis		
Yes (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
No (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Liver metastasis		
Yes (n = 3)	33.3 (0.8–90.6)	66.7 (9.4–99.2)
No (n = 18)	38.9 (17.3–64.3)	83.3 (58.6–96.4)
PD-L1 expression		
CPS ≥ 1 (n = 16)	37.5 (15.2–64.6)	81.3 (54.4–96.0)
CPS < 1 (n = 5)	40.0 (5.3–85.3)	80.0 (28.4–99.5)



Source: Company data, CMBIGM

HLX43 demonstrated favourable safety profile with low hematologic toxicity, which support its future expansion into 1L therapy and combination regimens. In the Phase 1b cohort, the rate of grade ≥3 TRAE was 42.9%, while no grade 3 or higher platelet count decreased and neutrophil count decreased were reported. The rate of grade ≥3 TRAE in anemia and lymphocyte count decreased were both only 14.3%.

Figure 7: Safety data of HLX43 Ph1b 2.0mg/kg

Median follow-up duration: 7.0 months

Summary of adverse events, n (%)	Phase 1b 2.0 mg/kg (n = 21)
Any TEAE*	21 (100)
≥ Grade 3**	11 (52.4)
≥ Grade 3 (≥ 10%)	
Anemia	3 (14.3)
Lymphocyte count decreased	3 (14.3)
Serious	11 (52.4)
Any TRAE	21 (100)
≥ Grade 3	9 (42.9)
TEAE leading to Tx interruption	10 (47.6)
TEAE leading to Tx discontinuation	2 (9.5)
TEAE leading to dose reduction	0
TEAE leading to death	3 (14.3)

Most common TEAEs (≥ 20%), n (%)	Phase 1b 2.0 mg/kg (n = 21)
Anemia	16 (76.2)
Decreased appetite	12 (57.1)
Nausea	11 (52.4)
Hypoalbuminemia	8 (38.1)
Neutrophil count decreased	8 (38.1)
White blood cell count decreased	8 (38.1)
Constipation	7 (33.3)
Hyponatremia	7 (33.3)
Vomiting	7 (33.3)
Alanine aminotransferase increased	6 (28.6)
Aspartate aminotransferase increased	6 (28.6)
Interleukin level increased	6 (28.6)
Hypertriglyceridemia	6 (28.6)
Lymphocyte count decreased	6 (28.6)
Hypochloremia	5 (23.8)
Pneumonia	5 (23.8)
Proteinuria	5 (23.8)
Weight decreased	5 (23.8)

* *No infusion-related reaction was reported in this study.*
** *No Grade 3 or higher platelet count decreased was reported; only 3 patients (14.3%, 3/21) experienced Grade 1 platelet count decreased.*
TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; Tx, treatment.

Source: Company data, CMBIGM

In the setting of IO-resistant NSCLC, Innovent's IBI363 (PD-1/IL-2) has set a high benchmark, in our view. In IO-resistant squamous NSCLC (with 39% of patients having received ⩾3 prior lines of therapy), IBI363 achieved a confirmed ORR (cORR) of 36.7%, an mPFS of 9.3 months, and a 12-month OS rate of 70.9%. In IO-resistant non-squamous NSCLC (28% with ≥3 prior treatments), the corresponding cORR, mPFS, and 12-month OS rate were 24.0%, 5.6 months, and 71.6%, respectively.

Henlius' HLX43 has also delivered competitive results, with a cORR of 33.3% across both squamous and non-squamous NSCLC subtypes, and an mPFS of 5.4 months in heavily pre-treated patients (62% with ⩾3 prior therapies). When compared with other novel

agents currently in development for IO-resistant NSCLC—such as AK112, SKB264, YL201, and BL-B01D1 (see cross-trial comparison below)—we believe HLX43 has shown encouraging efficacy that supports further clinical advancement. Multiple Ph2 trials of HLX43 across a broad range of solid tumors are currently ongoing.

Figure 8: Cross-trial comparison of therapies in IO-resistant NSCLC

Drug	IBI363		AK112	SKB264		YL201		BL-B01D1	HLX43	
MoA	PD-1/IL-2 bsAb		PD-1/VEGF bsAb	TROP2 ADC		B7-H3 ADC		EGFR/HER3 ADC	PD-L1 ADC	
Company	Innovent		Akeso/Summit	Kelun-Biotech/MSD		MediLink		Biokin Pharma/BMS	Henlius	
Dose and regimen	IBI363 mono at 3mg/kg and lower dose levels		AK112 + docetaxel; AK112 10mg/kg or 20mg/kg Q3W	SKB264 mono; 5mg/kg Q2W		mono, 2.0/2.4 mg/kg		mono 2.5/3.0/3.5/5.0/6.0mg /kg	mono 2mg/kg	
Trial ID	NCT05460767		NCT04900363	NCT04152499		NCT05434234, NCT06057922		NCT05194982	NCT06115642	
Stage	Ph1a/1b		Ph1b/2	Ph2		Ph1		Ph1	Ph1b	
Patient no.	136		20	21		68		62	21	
Baseline	later-line IO-treated sq- and nsq-NSCLC; 39% with ≥3 prior treatment for sq-NSCLC; 28% with ≥3 prior treatment for nsq-NSCLC		Progressed after platinum-doublet and PD-1	EGFR-wt; median prior 3 lines therapies including PD-(L)1		EGFR-wt, 96% with prior PD-(L)1		All had prior chemo, 90% (45/50) had prior anti-PD-1/L1 and chemo	IO resistant; 62% with ≥3 prior treatment (median 3 lines)	
Follow-up for PFS	10.1 vs 21.9 months	11.3 vs 16.5 months	16.8 months	17.2 months				as of Aug 2023	7.0 months as of Mar 2025	
No. of pts	nsq-NSCLC (n=55) 25 pts in 3mg/kg vs 30 pts in 0.6/1/1.5mg/kg	sq-NSCLC (n=57) 30 pts in 3mg/kg vs 27 pts in 1/1.5mg/kg	nsq-NSCLC (n=13), sq-NSCLC (n=7)	nsq-NSCLC (n=9)	sq-NSCLC (n=12)	nsq-NSCLC (n=54, adeno 28, LELC 24)	sq-NSCLC (n=14)	NSCLC (n=62)	nsq-NSCLC (n=6)	sq-NSCLC (n=15)
ORR	ORR 28.0% vs 17.2% cORR 24.0% vs 13.8%	ORR 43.3% vs 25.9% cORR 36.7% vs 25.9%	40%	22.2%	30.0%	28.6% for adeno, 54.2% for LELC	8.3%	40.3% (cORR 30.6%)	33.3% (cORR 33.3%)	40.0% (cORR 33.3%)
mPFS	**5.6** vs 2.7 (3mg vs 0.6/1/1.5mg)	**9.3** vs 5.5 (3mg vs 1/1.5mg)	**7.1**	**5.8**	**5.1**	4.2 for adeno, 8.1 for LELC	4.1	5.4	5.4	
mOS	**17.5 vs NC**	15.3 vs NC	15.6	16.2	12.8					
12-month OS rate	**71.6%** vs 58.2%	**70.9%** vs 58.2%	65%	66.7%	50.0%					
Grade ≥3 TRAE	43.9% (3mg/kg)		41% for sq, 19% for nsq	69.8%		54.5%			42.9%	
TRAE leading to discontinuation	7.0% (3mg/kg)		11% for sq, 3% for nsq			5.4%			9.5% (TEAE leading)	
TRAE leading to death	0 (3mg/kg)		0 for sq, 4% for nsq			2.6%				
Source	Link Link		Link	Link		Link		Link	Link Link	

Source: Pubmed, ASCO, CMBIGM

Pfizer's early data further verify the PD-L1 ADC concept

As the first mover in the PD-L1 ADC space, Pfizer's SGN-PDL1V (PDL1V) is an investigational ADC that delivers the cytotoxic agent MMAE to cells expressing PD-L1. In addition to cytotoxicity, PDL1V also elicits antitumor activity via the bystander effect and immunogenic cell death. PDL1V has demonstrated encouraging data which further verify the PD-L1 ADC concept. At 2025 ASCO meeting, updated Ph1 results for PDL1V as monotherapy in NSCLC and initial data of PDL1V in combination with pembrolizumab in patients with first-line HNSCC were released. These data provide additional support for the initiation of the two pivotal Ph3 trials planned for PDL1V in 2H25 in second line+ NSCLC and first line HNSCC.

PDL1V mono in NSCLC

For SoC failed NSCLC, in a Ph1 trial (NCT05208762, link), as of 20 Dec 2024, 30 NSCLC patients have been treated with PDL1V mono at the recommended expansion dose of 1.5mg/kg on days 1 and 8 of a 21-day cycle (2Q3W). 23.3% of the patients had squamous histology, and 83.3% were PD-L1 positive. The median number of prior lines of therapy was 2.0 (1, 8). 96.7% and 66.7% of patients were previously exposed to anti-PD-1/PD-L1 antibodies and taxanes, respectively.

With median follow-up of 10.0 months, the cORR for patients with NSCLC was 26.7%, while the cORR was 32.0% for those with PD-L1 expressing tumors. The median duration of confirmed response was 7.8 months. Objective responses were observed in patients with PD-L1 expressing squamous (n=6) and non-squamous (n=19) tumors (33.3% and 31.6% cORR, respectively).

As mentioned previously, HLX43 delivered 37.5% ORR for CPS ≥1 NSCLC patients who has a median 3.0 lines of prior treatment, which were better than PDL1V's 32.0% ORR for patients with better baseline (median 2.0 lines of prior lines of therapy), showing the best-in-class potential of HLX43, in our view.

PDL1V monotherapy at the recommended expansion dose was generally well tolerated with a manageable safety profile. In PDL1V's trial for NSCLC, there have been no dose-limiting toxicities at the recommended expansion dose. Peripheral sensory neuropathy (27.2%), nausea (25.0%), diarrhea (23.9%), and fatigue (21.7%) were the most common TRAEs for all patients treated in the Phase 1 trial at the recommended expansion dose (N=92). 5.4% of patients discontinued therapy due to TRAEs. The most common grade ≥3 TRAE was anemia (5.4%). The incidence of treatment-related immune-mediated AEs was 14.1%; 5.4% for grade 3, with no grades 4 or 5.

PDL1V in combination with pembrolizumab in 1L HNSCC

We also see the potential of PD-L1 ADC in combination with PD-1 mAbs in front-line treatment. For instance, Pfizer's PDL1V + pembrolizumab has demonstrated early encouraging ORR and CR in 1L PD-L1 positive HNSCC as observed in its Ph1 trial. The Part D of the Ph1 trial (NCT05208762) assessed PDL1V and pembrolizumab combination in patients with untreated R/M HNSCC with PD-L1 CPS ⩾1. As of 20 Dec 2024 (link), 14 patients were dosed. Eight patients received 1.25 mg/kg and 6 received 1.5 mg/kg; 64.3% were P16 positive oropharyngeal, and 57.1% had CPS 1–<20.

The investigator-assessed ORR was 50.0% among 14 response-evaluable patients, with a complete response (CR) rate of 21.4%. Recall that in the KEYNOTE-048 trial, pembrolizumab in combination with chemotherapy achieved ORR of 36% in first-line HNSCC patients with PD-L1 CPS ≥1. This result fall short of the 50% ORR observed with the PDL1V and pembrolizumab combination in this cross-trial comparison, supporting the therapeutic rationale of combining PD-L1 ADCs with PD-1 inhibitors in first-line cancer treatment.

On the safety side, the combination of PDL1V and pembrolizumab was generally well tolerated with no DLTs. The most frequent grade ≥3 TRAEs were diarrhea (14.3%) and anemia, decreased appetite, fatigue, and neutropenia (7.1% each). Treatment-related immune-mediated AEs by investigator assessment were observed in 7.1% of patients; 7.1% grade 3.

Comprehensive cancer coverage of HLX43 as one of the most advanced PD-L1 ADCs

Globally, HLX43 is one of the most advanced PD-L1-targeting ADCs in clinical development, and the second to enter clinical trials. Pfizer is about to initiate Ph3 studies of SGN-PDL1V (a PD-L1 ADC) in 2H25, while HLX43 stands out as a strong contender in this emerging therapeutic class.

Figure 9: Global PD-(L)1 targeted ADCs in clinical stage of development

Drug candidate	MoA	Company	Global highest phase	US highest phase	China highest phase
HLX43	PDL1 ADC	Henlius;MedLink	Ph2	Ph2	Ph2
PF-08046054	PDL1 ADC	Seagen (Pfizer)	Ph1	Ph1	IND
DB-1419	PDL1/B7-H3 ADC	Duality Bio	Ph1/2	Ph1/2	Ph1/2
BPT567	PD1 ADC (IL-18 payload)	Bright Peak Therapeutics	Ph1/2	Ph1	-
IBI3014	PDL1/TROP2 ADC	Innovent	Ph1/2	-	Ph1/2

Source: PharmCube, CMBIGM

Preclinical studies and a Ph1 clinical trial have demonstrated that HLX43 exhibits robust anti-tumor activity and a favorable safety profile in NSCLC and other PD-(L)1-resistant tumour types (link). Henlius is actively progressing multiple Ph2 proof-of-concept (PoC) trials evaluating HLX43 monotherapy across a broad spectrum of tumor types, including NSCLC, head and neck squamous cell carcinoma (HNSCC), nasopharyngeal carcinoma (NPC), cervical cancer (CC), esophageal squamous cell carcinoma (ESCC), and hepatocellular carcinoma (HCC). In parallel, a Ph1b/2 study has been initiated to investigate HLX43 in combination with a PD-1 monoclonal antibody in solid tumors, especially NSCLC.

Figure 10: Broad indications targeted by HLX43 (PD-L1 ADC) (as of Apr 2025)

Indication	Trial ID	Regimen	Trial phase	Region	Release date	Completion date	Patient No.
NSCLC: prior PD-(L)1 and chemo failed for pts without AGA; prior TKI failed for pts with AGAs	NCT06907615	HLX43, single arm, two doses	Phase II	China	2025-04-02	2028-06-04	243
HNSCC: failed prior systemic treatment	NCT06857279	HLX43, single arm, three doses	Phase II	China	2025-03-04	2028-07-15	90
3L+ NPC: failed to 2L therapy	NCT06839066	HLX43, single arm, three doses	Phase II	-	2025-02-21	2027-11-22	90
2L+ CC: failed to 1L therapy	NCT06769152	HLX43, single arm, three doses	Phase II	China	2025-01-10	2027-06-05	60
2L+ ESCC: failed to 1L therapy	NCT06769113	HLX43, single arm, three doses	Phase II	China	2025-01-10	2027-06-05	60
2L+ HCC: failed at least one line of PD-1-based combo, lenvatinib, or sorafenib	NCT06742892	HLX43, single arm, three doses	Phase II	China	2024-12-19	2027-06-05	90
Solid tumors Ph1b: solid tumor failed prior treatment; Ph2: EGFRm NSCLC failed TKI, chemo	NCT06848699	HLX43 in combo with serplulimab (PD-1), single arm, five doses	Phase I/II	China	2025-02-27	2027-10-01	105
Solid tumors who failed prior treatment	NCT06115642	HLX43	Phase I	China	2023-11-03	2025-11-30	36

Source: Company data, CMBIGM

HLX43 sales forecast

We expect HLX43 to receive regulatory approval in China by 2029E, followed by overseas approvals starting in 2030E, initially targeting second-line IO-resistant wild-type NSCLC. Approvals for additional solid tumor indications—such as NPC, CC, ESCC, and HCC—are anticipated to follow. We forecast HLX43's risk-adjusted peak sales in China to reach RMB1.87bn by 2034E. In international markets, we expect the risk-adjusted peak sales to reach US$1.10bn by 2036E, which could generate approximately US$130mn (or RMB936mn) in royalty income for Henlius, assuming a 12% revenue-sharing agreement.

Figure 11: HLX43 China sales forecast (RMBmn)

HLX43 sales projection – China	Stage	Year of approval	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
2L IO-resistant wild-type NSCLC	Ph2	2029E	607	1,203	2,189	3,032	3,847	4,675	4,667	4,492	4,318	4,144	3,972
Probability of success in China			30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Other indications	Multiple Ph2 trials in various tumors	2030E		64	164	303	385	468	467	449	432	414	397
Risk-adjusted China sales			**182**	**424**	**821**	**1,213**	**1,539**	**1,870**	**1,867**	**1,797**	**1,727**	**1,658**	**1,589**

Source: CMBIGM estimates

Figure 12: HLX43 overseas sales forecast (US$mn)

HLX43 sales projection – exChina	Stage	Year of approval	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
2L IO-resistant wild-type NSCLC	To start global Ph2	2030E		147	450	831	1,294	1,848	2,321	2,395	2,382	2,366	2,347
Probability of success in the US				30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
HLX43 US sales in other indications					24	44	69	98	123	127	126	125	124
Risk-adjusted sales from US				44	159	293	457	652	819	845	841	835	829
Risk-adjusted sales from EU				13	48	88	137	196	246	254	252	251	249
Risk-adjusted sales from ex-China				**57**	**207**	**381**	**594**	**848**	**1,065**	**1,099**	**1,093**	**1,086**	**1,077**
% of royalty				*10%*	*10%*	*11%*	*11%*	*11%*	*12%*	*12%*	*12%*	*12%*	*13%*
Sales royalty				6	21	40	65	95	122	130	132	135	137
Upfront & milestone payment				-	-	-	-	-	-	-	-	-	-
Total income from ex-China (US$ mn)				**6**	**21**	**40**	**65**	**95**	**122**	**130**	**132**	**135**	**137**
Total income from ex-China (RMB mn)				**41**	**154**	**292**	**467**	**686**	**884**	**936**	**955**	**972**	**988**

Source: CMBIGM estimates

HLX22 (HER2 mAb), an overwhelming alternative for 1L HER2+ gastric cancer

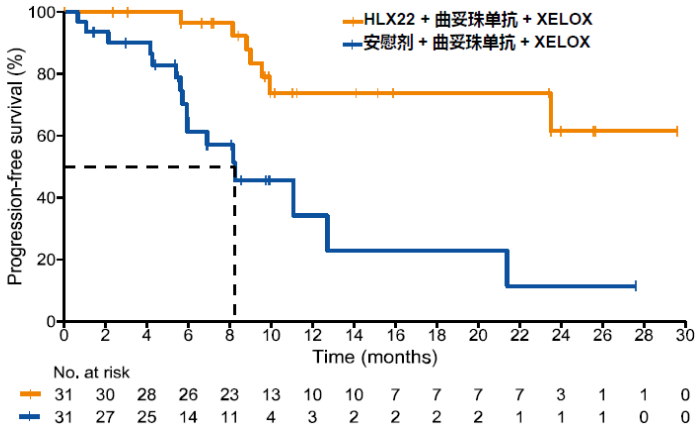
HLX22 shows best-in-class potential in 1L HER2+ gastric cancer, with overwhelming efficacy and global partnership opportunity

We believe HLX22, in combination with trastuzumab, has the potential to become a highly differentiated first-line treatment for HER2-positive gastric cancer, supported by compelling Ph2 efficacy data that suggest a meaningful advantage over current standard of care (SoC). If confirmed in ongoing Ph3 trials, HLX22 could significantly shift the treatment paradigm in this population, in our view, which accounts for approximately 12–23% of gastric and gastroesophageal junction cancer (G/GEJC) patients.

HLX22 is a novel monoclonal antibody targeting HER2 subdomain IV, similar to trastuzumab but binding to non-overlapping epitopes. The dual targeting of distinct HER2 subdomain IV epitopes with HLX22 and trastuzumab has been shown to enhance internalization of HER2/HER2 homodimers and HER2/EGFR heterodimers by 40-80% (link), leading to potent anti-tumor activity in HER2-positive gastric cancer models.

In a Ph2 clinical trial, the combination of HLX22 (15 mg/kg) + trastuzumab + chemotherapy demonstrated a median progression-free survival (mPFS) not reached at a median follow-up of 20.3 months (link), versus 8.2 months in the SoC arm (trastuzumab + chemo). The hazard ratio of mPFS was an impressive 0.20 (95% CI: 0.06–0.45), indicating a substantial reduction of 80% in risk of progression compared to the current standard care treatment. The safety profile was manageable, with Grade ⩾3 treatment-related adverse events (TRAEs) reported in 29% vs 19% of patients in the treatment and control arms, respectively.

Figure 13: Ph2 results of HLX22 + trastuzumab + chemo in 1L HER2+ GC



	HLX22 组 (n = 31)	安慰剂组 (n = 31)
mPFS, months (95% CI)	NR (23.5–NE)	8.3 (5.7–12.7)
HR (95% CI)	0.2 (0.06–0.45)	p<0.0001
12-month PFS rate (95% CI)	73.8 (50.3–87.4)	34.2 (12.0–58.1)
24-month PFS rate (95% CI)	61.5 (30.4–82.0)	11.4 (0.8–38.1)
mOS, months (95% CI)	NR (23.5–NE)	22.0 (10.6–NE)
HR (95% CI)	0.5 (0.20–1.21)	p=0.1174

As of Jun 30, 2024, the median follow-up periods for the HLX22 and placebo arms were 20.3 and 24 months, respectively.

Source: Henlius, CMBIGM

Based on the overwhelming Ph2 results, if confirmed in Ph3 study, we believe HLX22 will be able to provide a more powerful treatment options than the SoC for the large HER2 positive gastric cancer first line treatment. A global Ph3 multi-regional clinical trial (MRCT) evaluating HLX22 + trastuzumab + chemo in the 1L HER2+ gastric cancer setting is ongoing (NCT06532006). The trial targets to enrol 550 patients globally across China, Japan, the US, Australia, and other regions, and has PFS and OS as the primary endpoints. In addition, in early 2025, HLX22 was granted orphan drug designation by the FDA for the treatment of gastric cancer, highlighting its potential value in an area of high unmet need.

We see significant global out-licensing potential for HLX22. Henlius originally in-licensed China rights to HLX22 from AbClon, Inc. in 2016 and subsequently secured global rights in 2018 at a relatively low in-licensing cost. The total upfront and option exercise payments amounted to US$11mn, with up to US$15.5mn in milestones and a single-digit royalty on annual net sales payable to AbClon.

Henlius is also expanding the application of HLX22 into HER2-expressing breast cancer. A Ph2 trial (NCT06832202) is ongoing to evaluate HLX22 in combination with Enhertu (trastuzumab deruxtecan) in second-line HER2-low, HR-positive breast cancer, a growing segment of unmet clinical need.

Figure 14: Comparison of therapies in 1L HER2+ GC

Clinical Trial	Highlight	Treatment Regimen	Enrollment (n)	Median PFS (months)	Median OS (months)	Median DOR (months)
HLX22-GC-201 (Ph2)	Ph3 MRCT ongoing in China, Japan, US, etc.	A: HLX22 (15mg/kg) + Trastuzumab + Chemo (XELOX) B: Trastuzumab + Chemo (XELOX)	ITT: 31 vs 31	NR vs 8.3 **HR=0.2** (95% CI: 0.06–0.45)	NR vs 22.0 **HR=0.5** (95% CI: 0.20–1.21)	NR vs 9.7 HR=0.1 (95% CI: 0.04–0.41)
KEYNOTE-811 (Ph3)	Approved by FDA and EMA for PD-L1+ subgroup	A: Pembrolizumab + Trastuzumab + Chemo (CF/XELOX) B: Trastuzumab + Chemo	ITT: 350 vs 348	10.0 vs 8.1 HR=0.73 (95% CI: 0.61-0.87)	20.0 vs 16.8 HR=0.80 (95% CI: 0.67-0.94), p=0.0040 (less than prespecified boundary 0.0201)	11.3 vs 9.5
			PD-L1+: 298 vs 296	10.9 vs 7.3 HR=0.72 (95% CI: 0.60-0.87)	20.1 vs 15.7 HR=0.79 (95% CI: 0.66–0.95)	11.5 vs 9.3
			PD-L1−: 52 vs 52	9.5 vs 9.5 HR=0.99 (95% CI: 0.62–1.56)	18.2 vs 20.4 HR=1.10 (95% CI: 0.72–1.68)	NA
ToGA (Ph3)	Current SoC	A: Trastuzumab + Chemo (CF/CX) B: Chemo (CF/CX)	Adjusted ITT: 294 vs 290	6.7 vs 5.5 HR=0.71, p=0.0002	13.8 vs 11.1 HR=0.74, p=0.0046	6.9 vs 4.8
			China Subgroup: 36 vs 48	6.8 vs 5.5 HR=0.69, p=NA	12.6 vs 9.7 HR=0.72, p<0.05	5.8 vs 4.5
JACOB (Ph3)	Ph3 failed	A: Pertuzumab + Trastuzumab + Chemo B: Trastuzumab + Chemo	ITT: 388 vs 392	8.5 vs 7.0 HR=0.73, p=0.001	17.5 vs 14.2 HR=0.84, p=0.057 (failed)	10.2 vs 8.4

Source: Henlius, Pubmed, CMBIGM

HLX22 sales forecast

We expect HLX22 to obtain regulatory approval in China by 2028E, followed by overseas approvals in 2029E, initially targeting first-line HER2-positive gastric cancer. Approvals for additional indications, including HER2-positive breast cancer, are anticipated to follow. We project risk-adjusted peak sales for HLX22 in China to reach RMB2.73bn by 2036E. In international markets, we expect HLX22's sales to reach US$886mn by 2039E, which could generate approximately US$115mn (or RMB831mn) in royalty income for Henlius, assuming a 13% revenue-sharing arrangement.

Figure 15: HLX22 China sales forecast (RMBmn)

HLX22 sales projection China	Stage	Year of approval	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
Gastric cancer	Global Ph3 in 1L HER2+ GC	2028E	156	492	1,024	1,712	2,211	2,471	2,737	3,008	2,948	2,889	2,831	2,774
PoS in China			*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
Breast cancer	Ph2 in HR+/HER2-low BC in China	2029E		136	525	981	1,506	1,682	1,858	2,035	2,211	2,210	2,209	2,208
PoS in China				*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*
Risk-adjusted China sales			**109**	**386**	**875**	**1,493**	**2,000**	**2,234**	**2,473**	**2,716**	**2,727**	**2,685**	**2,644**	**2,604**

Source: CMBIGM estimates

Figure 16: HLX22 overseas sales forecast (US$mn)

HLX22 sales projection China	Stage	Year of approval	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E
Gastric cancer	Global Ph3	2029E	6	27	57	97	128	146	150	155	159	164	169
PoS in China			*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
Breast cancer	-	2030E	-	95	308	616	1,028	1,444	1,734	1,769	1,804	1,840	1,877
PoS in China			*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*
Risk-adjusted sales from US			4	47	132	253	398	535	625	639	653	667	681
Risk-adjusted sales from EU			1	14	40	76	119	161	188	192	196	200	204
Risk-adjusted sales from ex-China			**5**	**61**	**172**	**329**	**517**	**696**	**813**	**830**	**848**	**867**	**886**
% of royalty			*10%*	*10%*	*11%*	*11%*	*11%*	*12%*	*12%*	*12%*	*12%*	*13%*	*13%*
Sales royalty			1	6	18	36	58	80	96	100	105	110	115
Upfront & milestone payment													
Total income from ex-China (US$ mn)			**1**	**6**	**18**	**36**	**58**	**80**	**96**	**100**	**105**	**110**	**115**
Total income from ex-China (RMB mn)			**4**	**46**	**132**	**259**	**418**	**578**	**692**	**725**	**760**	**795**	**831**

Source: CMBIGM estimates

Serplulimab (PD-1) represents a compelling opportunity in large underserved first-line MSS CRC indication

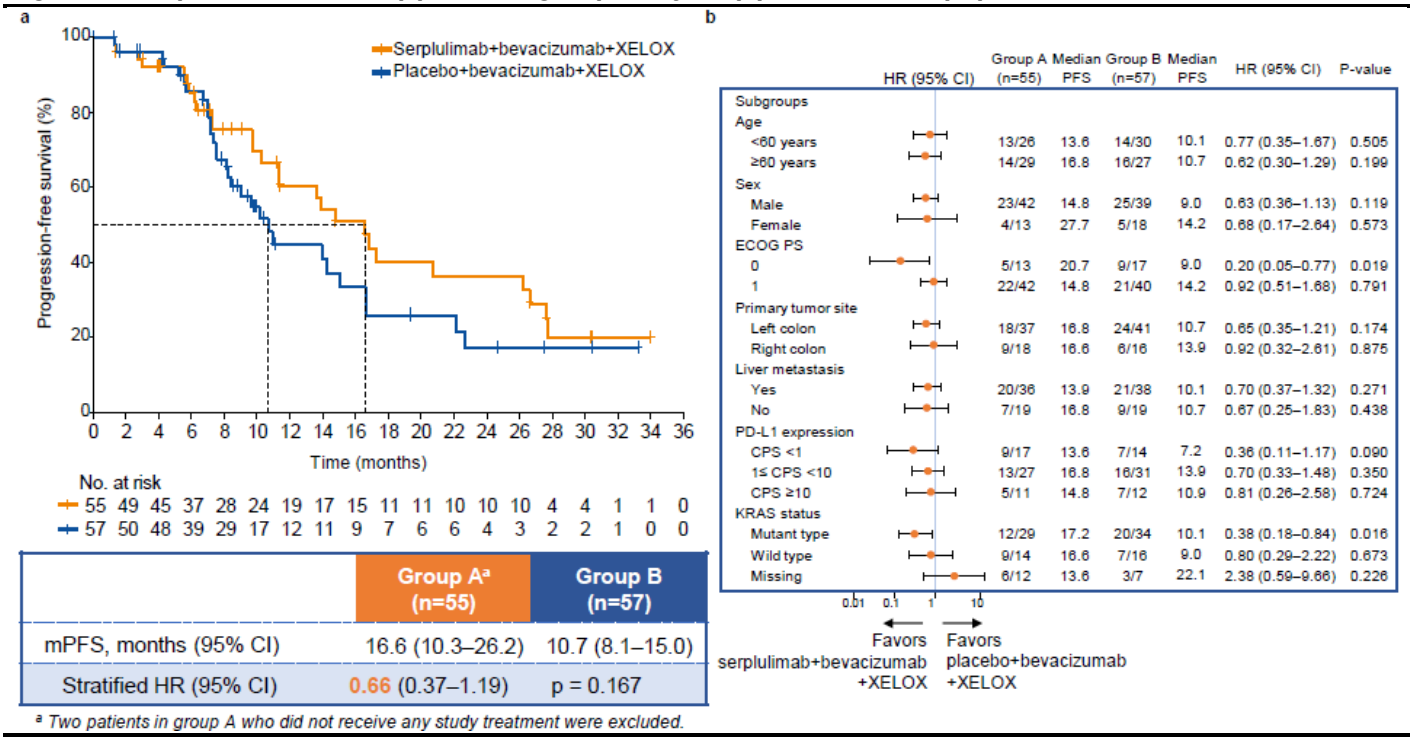
Compelling upside potential for serplulimab in MSS CRC

Henlius is actively expanding the clinical footprint of serplulimab, its PD-1 inhibitor already approved in China for several front-line indications including ES-SCLC, non-squamous/squamous NSCLC, ESCC, and MSI-H solid tumors. Notably, the Company is running multiple Ph3 trials in 1L MSS CRC, perioperative gastric cancer, and 1L LS-SCLC, targeting broader commercial opportunities across high-incidence cancers.

In particular, we view the serplulimab + bevacizumab + chemotherapy regimen as a promising first-line option in microsatellite stable colorectal cancer (MSS CRC), which accounts for ~85% of all CRC cases in China (link). CRC is the second most prevalent cancer in China, yet I/O agents have shown limited efficacy in the microsatellite stable (MSS) subtypes, underscoring the need for effective new treatment strategies. MSS subtype CRC has the proficient DNA mismatch repair (pMMR) system to normally corrected errors in the DNA sequences. The immune microenvironment of MSS CRC is primarily characterized by low levels of tumor-infiltrating lymphocytes (TILs) and low tumor mutational burden, which making it a prototypical "cold tumor".

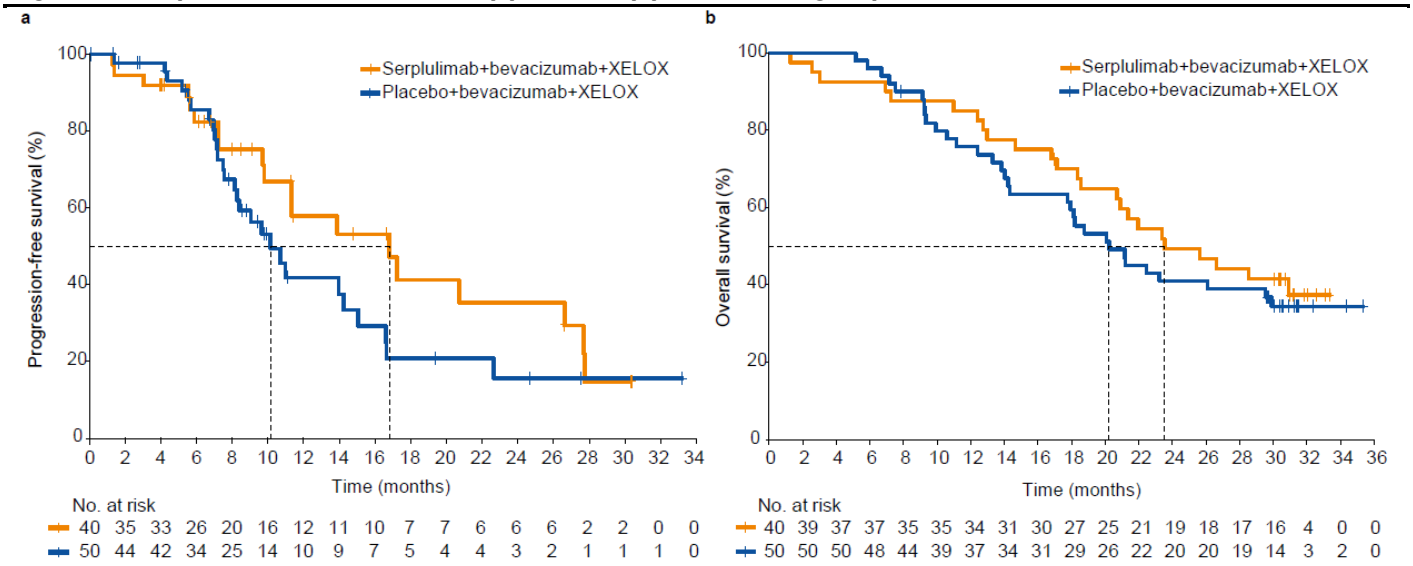
Serplulimab has demonstrated encouraging Ph2 data in 1L MSS CRC, which supports its continued development. In a randomized Ph2 trial (n=114), patients with stage IV CRC were assigned 1:1 to receive either serplulimab + bevacizumab + chemo (Group A) or bevacizumab + chemo (Group B). Among the 94 patients with available MSI status, 90 (96%) were MSS. As of the cutoff in Jun 2024 (median follow-up 31 months), the Group A showed a numerically longer PFS (16.6 vs 10.7 months; HR 0.66) and OS (25.6 vs 21.2 months; HR 0.86). In the MSS subgroup, the trend persisted with PFS of 16.8 vs 10.1 months (HR 0.65) and OS of 23.5 vs 20.2 months (HR 0.79), suggesting potential benefit in this difficult-to-treat population.

Figure 17: Kaplan Meier curve (a) and subgroup analysis (b) of PFS in ITT population of Ph2 in CRC



Source: Company data, CMBIGM

Figure 18: Kaplan Meier curve of PFS (a) and OS (b) in MSS subgroup of Ph2 in CRC



	Group A (n=40)	Group B (n=50)
mPFS, months (95% CI)	16.8 (9.8–27.7)	10.1 (8.1–15.0)
Stratified HR (95% CI)	0.65 (0.33–1.29)	p = 0.211

	Group A (n=40)	Group B (n=50)
mOS, months (95% CI)	23.5 (18.5–NE)	20.2 (14.3–29.9)
Stratified HR (95% CI)	0.79 (0.45–1.38)	p = 0.399

Source: Company data, CMBIGM

In the Ph2 study, serplulimab + bevacizumab + chemotherapy demonstrated a notable absolute improvement in both mPFS (+6.7 months) and mOS (+3.3 months) in the MSS population—an encouraging signal in a setting where prior I/O combinations have struggled to show meaningful benefits. Previously, atezolizumab + SoC in the AtezoTRIBE trial (link) achieved only a 1.6-month mPFS improvement (13.0 vs 11.5 months; HR 0.79) in 1L MSS mCRC, while nivolumab + SoC in the CheckMate 9X8 study (link) failed to extend PFS over standard of care (mPFS: 11.9 vs 11.9 months). Against this backdrop, the serplulimab regimen's differentiated efficacy profile in MSS CRC appears promising.

Figure 19: Comparison of clinical results in 1L MSS CRC

Product	Clinical trial	Treatment regimen	Enrollment (n)	Median PFS (months)	Median OS (months)	Median DOR (months)
Serplulimab + SoC	HLX10-015-CRC301 (Ph2) Data cutoff: Jun 2024; Median follow-up 31.0 months	A: Serplulimab + Bevacizumab + Chemo (XELOX) B: Bevacizumab + Chemo (XELOX)	ITT: 55 vs 57	16.6 vs 10.7, p=0.17 HR=0.66 (95% CI, 0.37–1.19)	NA	17.7 vs 11.3, p=0.041 HR=0.45 (95% CI, 0.20–0.98)
			MSS Subgroup: 40 vs 50	**16.8** vs 10.1, p=0.21 **HR=0.65** (95% CI, 0.33–1.29)	23.5 vs 20.2, p=0.40 HR=0.79 (95% CI, 0.45–1.38)	16.3 vs 9.3, p=0.045 HR=0.39 (95% CI, 0.15–1.00)
Atezolizumab + SoC	AtezoTRIBE (Ph2)	A: Atezolizumab + Bevacizumab + chemo (FOLFOXIRI) B: Bevacizumab + chemo (FOLFOXIRI)	ITT: 145 vs 73	13.1 vs 11.5 HR=0.71, p=0.015	33 vs 27.2 HR=0.81, p=0.136	NA
			pMMR Subgroup: 134 vs 67	13.0 vs 11.5 HR=0.79, p=0.073	30.8 vs 26.9 HR=0.83, p=0.172	NA
Nivolumab + SoC	CheckMate 9X8 (Ph2)	A: Nivolumab + Bevacizumab + chemo (mFOLFOXIRI) B: Bevacizumab + chemo (mFOLFOXIRI)	ITT: 127 vs 68	11.9 vs 11.9 HR=0.81, p=0.33 (failed)	29.2 vs NR HR=1.03, p NA	12.9 vs 9.3 HR NA, p NA
Bevacizumab + Chemotherapy (SoC)	Ph3 (link)	A: Bevacizumab + chemo (FOLFOXIRI) B: Chemo (FOLFOXIRI)	ITT: 402 vs 411	10.6 vs 6.2 HR=0.54, p<0.001	20.3 vs 15.6 HR=0.66, p<0.001	10.4 vs 7.1 HR=0.62, p=0.001
HLX04 (Bevacizumab biosimilar only)	HLX04 (Ph3, Bioequivalence Study)	A: HLX04 + Chemo (mFOLFOX6 or XELOX) B: Bevacizumab + Chemo (mFOLFOX6 or XELOX)	ITT: 338 vs 337	11.4 vs 12.4 HR=1.07 (95% CI, 0.83–1.37)	20.7 vs 22.4 HR=1.03 (95% CI, 0.84–1.25)	11.1 vs 12.3 HR=1.14 (95% CI, 0.80–1.61)

Source: Company data, PharmCube, CMBIGM

In the Ph2 study, serplulimab continues to show a favorable risk-benefit profile in 1L CRC, supporting its potential label expansion beyond MSI-H tumors. The addition of serplulimab to bevacizumab + chemotherapy demonstrated a manageable safety profile, with grade ≥3 treatment-related adverse events (TRAEs) observed in 70.9% of patients in the serplulimab arm (Group A) versus 59.6% in the control arm (Group B). Serious TRAEs related to serplulimab or placebo occurred in 45.5% and 36.8%, respectively. Grade 5 TEAEs of disease progression that led to death were comparable between groups (7.3% vs 7.0%).

Although the Ph2 study did not achieve statistical significance due to small sample size, the clinically meaningful improvements in progression-free and overall survival offer a strong rationale for further development. Building on this signal, Henlius has already advanced the regimen into a pivotal Ph3 trial, targeting the high-unmet-need MSS CRC patient population with limited treatment options. The Ph3 study (NCT04547166), with PFS as the primary endpoint, is currently ongoing in China, Japan, and other Asian regions.

Biosimilars: to seize the large opportunity in global biosimilar markets

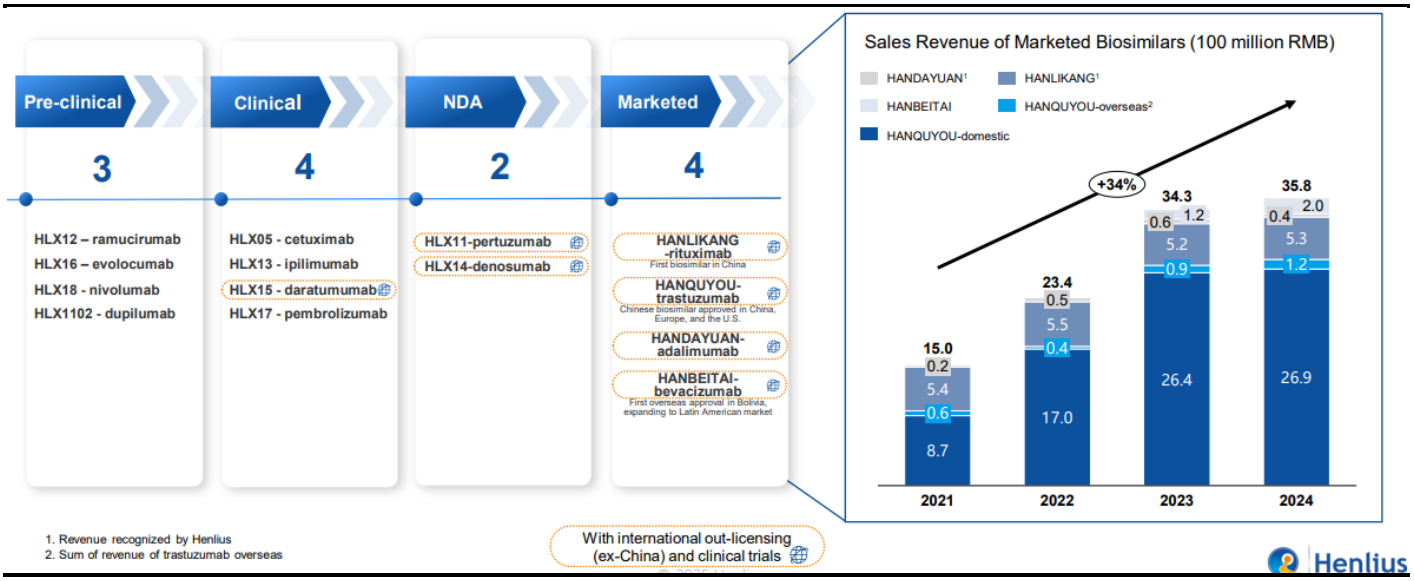
Expect fast growth from overseas biosimilar sales supported by strong partnerships

In China, Henlius has successfully launched four biosimilars as well as the innovative drug serplulimab. In 2024, the Company reported total drug sales of RMB4.93bn, including RMB3.58bn from biosimilars. Biosimilars have become a core cash-generating business, providing strong financial support for Henlius's continued investment in innovative drug R&D.

More importantly, Henlius is at the forefront of internationalizing Chinese biosimilars, leading the domestic biotech industry in overseas registration and commercialization. To date, the Company has obtained regulatory approvals for its trastuzumab biosimilar in both the US and EU, and for bevacizumab and rituximab biosimilars in Latin America.

In addition, serplulimab (PD-1), Henlius's flagship innovative immuno-oncology therapy, has been approved in the EU and is actively seeking regulatory approval in the US. The Company is also advancing its global biosimilar portfolio: marketing authorization applications (MAAs) for HLX14 (denosumab biosimilar) have been accepted in the EU, US, and Canada, while MAAs for HLX11 (pertuzumab biosimilar) have been accepted in both the US and EU.

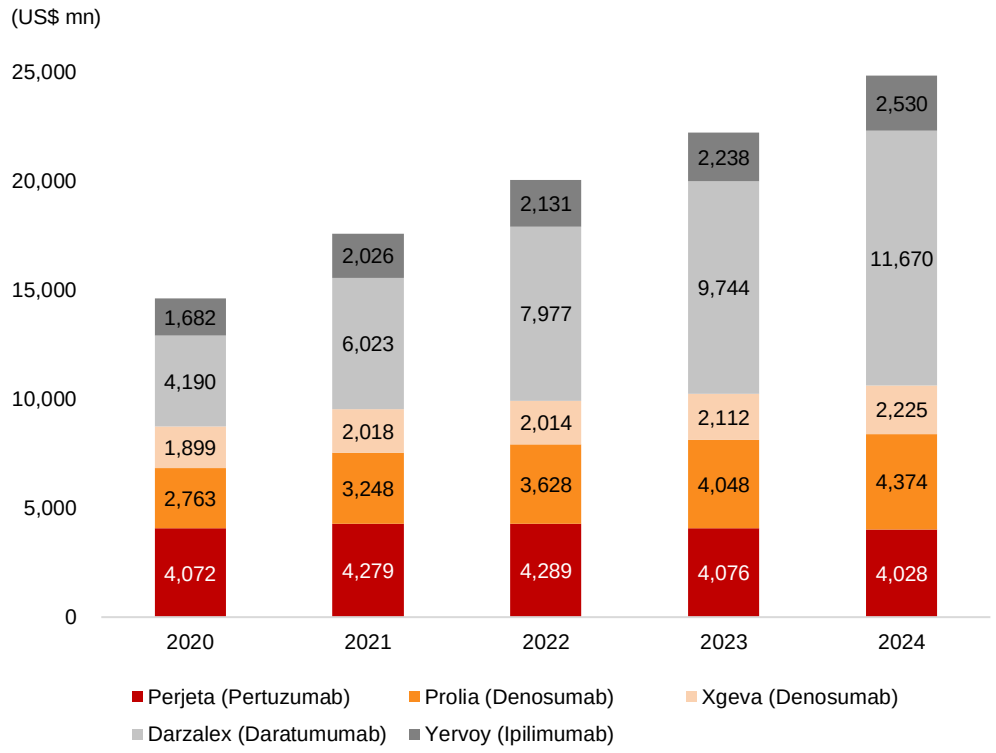
Figure 20: Robust biosimilar pipeline aiming at global market



Source: Company data (as of Mar 2025), CMBIGM. Note: in Apr 2025, Henlius further out-licensed HLX13-Ipilimumab (CTLA-4) to Sandoz.

Currently, Henlius is developing multiple potential blockbuster biosimilars, especially the pertuzumab biosimilar, denosumab biosimilar, daratumumab biosimilar, and ipilimumab biosimilar. Notably, the pertuzumab biosimilar, for which the Company submitted a MAA to the US FDA in Jan 2025, may become the first-to-market biosimilar in the US. The combined global sales of the four reference biologics reached US$24.8bn in 2024, underscoring the significant market potential for their biosimilar counterparts.

Figure 21: Global sales of several original biological drugs



Source: Pharmcube, CMBIGM

Henlius has forged extensive global partnership network surrounding its various biosimilars, with Accord, Sandoz, Dr. Reddy's, Eurofarma, KGbio, and Organon, etc. Henlius is well-positioned to expand its international commercial footprint efficiently, in our view. As of year-to-date 2025, the Company has successfully out-licensed two biosimilar assets to global partners:

In Feb 2025, Henlius granted Dr. Reddy's the rights to develop, manufacture, and commercialize HLX15 (daratumumab biosimilar) in the US and certain European markets. Henlius will receive up to US$131.6mn, including an upfront payment of US$33mn and tiered royalties based on future sales.

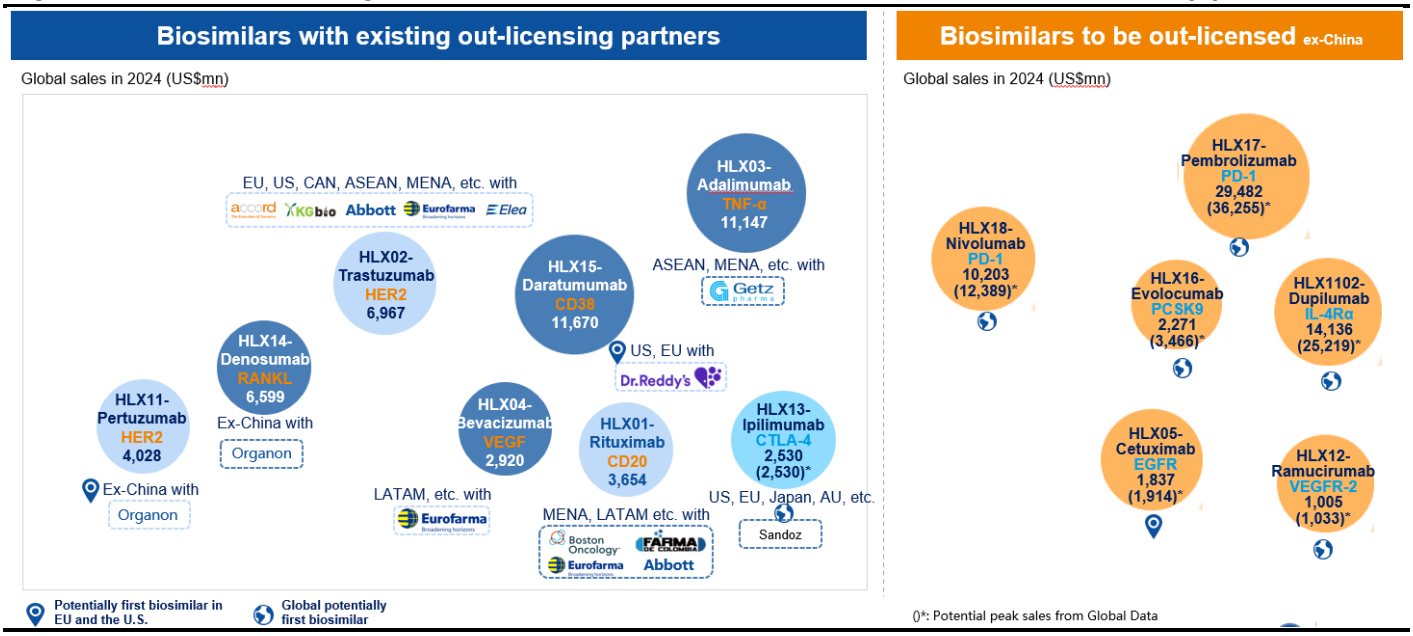
In Apr 2025, Henlius entered into a licensing agreement with Sandoz, granting it exclusive overseas commercialization rights for HLX13 (ipilimumab biosimilar). The deal is valued at up to US$301mn, including an upfront payment of US$31mn, with additional milestone payments linked to sales performance.

Figure 22: Henlius' product development in overseas markets

Generic Name	Brand name	Approved countries/regions	Approval time	Indications	Overseas commercial partners
Trastuzumab biosimilar	Hanquyou	United States, European Union, Canada, Southeast Asia, Latin America	2024 (US), 2020 (EU)	Adjuvant treatment of breast cancer, metastatic breast cancer, and metastatic gastric cancer	Abbott, Accord, Eurofarma, PT Kalbio Global Medika, Laboratorio ELEA, Phoenix S.A., Getz Pharma
Serplulimab (Innovative)	Hansizhuang	European Union, Southeast Asia	2025 (EU)	First-line treatment of extensive-stage small cell lung cancer (ES-SCLC)	KGBio, Intas, Fosun Pharma
Rituximab biosimilar	Hanlikang	Latin America	2024 (Latin America)	Non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis	Abbott, Boston Oncology, LLC, Eurofarma, FARMA DE COLOMBIA S.A.S
Bevacizumab biosimilar	Hanbeitai	Latin America	2024	Metastatic colorectal cancer, advanced non-small cell lung cancer, recurrent glioblastoma, etc.	Eurofarma, Abbott
Adalimumab biosimilar	Handayuan	Pakistan	2024	Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, etc.	Getz Pharma
Denosumab Biosimilar	HLX14	United States, European Union (applications accepted)	Expected 2025	Postmenopausal osteoporosis (Phase 3 endpoints met in April 2024)	Organon
Pertuzumab Biosimilar	HLX11	United States, European Union (applications accepted)	Expected 2025	HER2-positive breast cancer (Phase 3 endpoints met in September 2024)	Organon
Daratumumab Biosimilar	HLX15	Phase 1	N/A	Multiple myeloma (under clinical development)	Dr. Reddy's
Ipilimumab biosimilar	HLX13	Phase 1	N/A	Melanoma, HCC (under clinical development)	Sandoz

Source: Company data, CMBIGM

Figure 23: Market size of originators and marketed biosimilars relevant to Henlius' biosimilar pipeline



Source: Company data (as of Mar 2025), CMBIGM

Furthermore, Henlius currently operates 48,000 liters of biologics manufacturing capacity, with plans to expand by an additional 36,000 liters in the long term. This robust infrastructure ensures sufficient global supply to support its expanding commercial portfolio.

Valuation

Figure 24: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT		1,468	670	947	1,302	1,594	2,055	2,755	3,467	4,049	4,680	5,089
Less: Tax		(220)	(103)	(148)	(204)	(251)	(324)	(434)	(547)	(642)	(746)	(819)
Depreciation and amortisation		468	459	452	445	367	361	356	352	348	344	341
CAPEX (incl. intangible assets)		(723)	(623)	(523)	(473)	(473)	(473)	(473)	(473)	(473)	(473)	(473)
Change in working capital		101	48	(58)	(66)	(3)	(49)	(92)	(130)	(17)	(52)	(8)
FCF		1,094	451	670	1,003	1,233	1,569	2,112	2,668	3,264	3,752	4,129
Terminal value												62,247

PV of enterprise (RMB mn)	33,115
Debt & Preferred Stock (RMB mn)	1,785
Deposit and pledged cash (RMB mn)	543
Equity value (RMB mn)	31,329
Value per share (RMB)	**57.64**
Value per share (HK$)	**61.98**
Terminal growth rate	**3.0%**
WACC	**9.83%**
Cost of Equity	2.5%
Cost of Debt	13.0%
Equity Beta	10.50 %
Risk Free Rate	1.05
Market Risk Premium	15%
Target Debt to Asset ratio	35%
Effective Corporate Tax Rate	65%

Source: CMBIGM estimates

Figure 25: Sensitivity analysis (HK$)

		WACC				
		8.83%	**9.33%**	**9.83%**	**10.33%**	**10.83%**
	4.0%	88.82	78.50	70.01	62.90	56.88
	3.5%	82.02	73.12	65.68	59.37	53.97
Terminal growth rate	**3.0%**	76.39	68.59	**61.98**	56.32	51.43
	2.5%	71.65	64.72	58.79	53.66	49.19
	2.0%	67.60	61.38	56.01	51.32	47.20

Source: CMBIGM estimates

Figure 26: CMBIGM estimates vs consensus

RMB mn	CMBIGM			Consensus			Diff (%)		
	FY25E	FY26E	FY27E	FY25E	FY26E	FY27E	FY25E	FY26E	FY27E
Revenue	6,581	4,763	5,441	5,954	6,382	7,409	11%	-25%	-27%
Gross profit	4,959	3,150	3,695	4,319	4,485	5,012	15%	-30%	-26%
Operating profit	1,468	670	947	790	891	1,038	86%	-25%	-9%
Net profit	1,244	585	836	786	874	1,140	58%	-33%	-27%
EPS (RMB)	2.29	1.08	1.54	1.44	1.66	2.11	59%	-35%	-27%
Gross margin	75.35%	66.14%	67.92%	72.53%	70.28%	67.64%	+2.82 ppt	-4.14 ppt	+0.28 ppt
Operating margin	22.30%	14.06%	17.40%	13.27%	13.96%	14.01%	+9.03 ppt	+0.10 ppt	+3.39 ppt
Net margin	18.91%	12.29%	15.37%	13.20%	13.69%	15.39%	+5.71 ppt	-1.40 ppt	-0.01 ppt

Source: Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Revenue	**3,215**	**5,395**	**5,724**	**6,581**	**4,763**	**5,441**
Cost of goods sold	(845)	(1,476)	(1,540)	(1,622)	(1,613)	(1,746)
Gross profit	**2,370**	**3,919**	**4,185**	**4,959**	**3,150**	**3,695**
Selling expense	(1,049)	(1,754)	(1,917)	(2,000)	(1,421)	(1,568)
Admin expense	(354)	(384)	(371)	(392)	(290)	(334)
R&D expense	(1,395)	(1,119)	(1,035)	(1,100)	(770)	(847)
Operating profit	**(428)**	**662**	**861**	**1,468**	**670**	**947**
Other gains/(losses)	(266)	(92)	(15)	(4)	19	37
EBITDA	**(163)**	**1,015**	**1,228**	**1,935**	**1,129**	**1,399**
EBIT	**(428)**	**662**	**861**	**1,468**	**670**	**947**
Pre-tax profit	**(694)**	**570**	**846**	**1,464**	**689**	**984**
Income tax	(1)	(24)	(25)	(220)	(103)	(148)
After tax profit	**(695)**	**546**	**820**	**1,244**	**585**	**836**
Minority interest	0	0	0	0	0	0
Net profit	**(695)**	**546**	**820**	**1,244**	**585**	**836**

BALANCE SHEET	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Current assets	**2,192**	**2,676**	**2,512**	**2,920**	**2,815**	**3,108**
Cash & equivalents	680	988	773	1,363	1,333	1,539
Restricted cash	0	0	0	0	0	0
Account receivables	456	648	857	649	623	650
Inventories	757	757	728	755	707	765
Other current assets	298	283	153	153	153	153
Non-current assets	**6,733**	**7,228**	**8,086**	**8,342**	**8,506**	**8,577**
PP&E	1,817	2,238	2,343	2,259	2,183	2,115
Right-of-use assets	412	415	357	285	213	141
Intangibles	4,332	4,511	5,355	5,767	6,079	6,291
Other non-current assets	171	64	30	30	30	30
Current liabilities	**5,002**	**5,067**	**5,032**	**4,452**	**3,926**	**3,453**
Short-term borrowings	2,522	2,800	2,560	2,060	1,560	1,060
Account payables	714	545	729	649	623	650
Other current liabilities	1,443	1,255	1,299	1,299	1,299	1,299
Contract liabilities	322	467	444	444	444	444
Non-current liabilities	**2,286**	**2,644**	**2,552**	**2,552**	**2,552**	**2,552**
Long-term borrowings	1,155	1,293	1,089	1,089	1,089	1,089
Deferred income	193	230	239	239	239	239
Other non-current liabilities	938	1,121	1,225	1,225	1,225	1,225
Total liabilities	**7,288**	**7,711**	**7,584**	**7,004**	**6,478**	**6,005**
Share capital	543	543	543	543	543	543
Retained earnings	1,093	1,649	2,470	3,714	4,300	5,136
Total shareholders equity	**1,636**	**2,192**	**3,014**	**4,258**	**4,843**	**5,680**
Minority interest	0	0	0	0	0	0
Total equity and liabilities	**1,636**	**2,192**	**3,014**	**4,258**	**4,843**	**5,680**

CASH FLOW	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	**(694)**	**570**	**846**	**1,464**	**689**	**984**
Depreciation & amortization	265	353	367	468	459	452
Tax paid	(1)	(21)	(28)	(220)	(103)	(148)
Change in working capital	1,101	61	(57)	101	48	(58)
Others	311	85	114	108	92	76
Net cash from operations	**982**	**1,048**	**1,242**	**1,921**	**1,185**	**1,306**
Investing						
Capital expenditure	(585)	(474)	(164)	(150)	(150)	(150)
Others	(774)	(531)	(746)	(573)	(473)	(373)
Net cash from investing	**(1,359)**	**(1,004)**	**(910)**	**(723)**	**(623)**	**(523)**
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	1,074	365	(408)	(500)	(500)	(500)
Proceeds from share issues	0	0	0	0	0	0
Others	(216)	(220)	(236)	(108)	(92)	(76)
Net cash from financing	**858**	**144**	**(643)**	**(608)**	**(592)**	**(576)**
Net change in cash						
Cash at the beginning of the year	155	673	868	773	1,363	1,333
Exchange difference	38	6	15	0	0	0
Cash at the end of the year	**680**	**868**	**571**	**1,363**	**1,333**	**1,539**

GROWTH	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Revenue	91.1%	67.8%	6.1%	15.0%	(27.6%)	14.2%
Gross profit	104.4%	65.3%	6.8%	18.5%	(36.5%)	17.3%
Operating profit	na	na	30.1%	70.4%	(54.4%)	41.4%
EBITDA	na	na	21.0%	57.6%	(41.7%)	23.9%
EBIT	na	na	30.1%	70.4%	(54.4%)	41.4%
Net profit	na	na	50.3%	51.7%	(53.0%)	42.9%

PROFITABILITY	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Gross profit margin	73.7%	72.6%	73.1%	75.4%	66.1%	67.9%
Operating margin	(13.3%)	12.3%	15.0%	22.3%	14.1%	17.4%
EBITDA margin	(5.1%)	18.8%	21.5%	29.4%	23.7%	25.7%
Return on equity (ROE)	(35.4%)	28.5%	31.5%	34.2%	12.9%	15.9%

GEARING/LIQUIDITY/ACTIVITIES	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Current ratio (x)	0.4	0.5	0.5	0.7	0.7	0.9

VALUATION	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
P/E	ns	45.2	30.1	19.8	42.2	29.5
P/B	15.0	11.3	8.2	5.8	5.1	4.3

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

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