

Comprehensive and Diversified Monoclonal Antibody Pipeline

	Product (Reference Drug)	Target	Indication	Pre-Clinical	IND	Phase 1	Phase 2 ⁽¹⁾	Phase 3	NDA
Biosimilar Portfolio	HLX01 (MabThera)	CD20	NHL ⁽²⁾	● First Chinese Biosimilar Approved according to the Biosimilar Guideline					
	HLX02 (Herceptin)	HER2	BC/mGC ⁽⁴⁾	● NDA accepted by NMPA and EMA					
	HLX03 (Humira)	TNF-α	PS/RA/AS ⁽⁷⁾	● NDA accepted by NMPA					
	HLX04 (Avastin)	VEGF	mCRC/nsNSCLC ⁽⁸⁾	●					
	HLX05 (Erbix) ⁽⁹⁾	EGFR	mCRC/SCCHN	●					
	HLX12 (Cyramza)	VEGFR2	Solid Tumors ⁽¹⁰⁾	●					
	HLX11 (Perjeta)	HER2	BC	●					
	HLX13 (Yervoy)	CTLA-4	Solid Tumors	●					
	HLX14 (Xgeva)	RANKL	Solid Tumors	●					
HLX15 (Darzalex)	CD-38	Multiple Myeloma	●						
Bio-innovative Portfolio	HLX01	CD20	RA ⁽¹¹⁾	●	●				
	HLX07	EGFR	Solid Tumors	●	●				
	HLX10	PD-1	Solid Tumors	●	●				
	HLX20	PD-L1	Solid Tumors	●	●				
	HLX06	VEGFR2	Solid Tumors	●	●				
	HLX04	VEGF	wAMD/DR ⁽¹¹⁾	●					
	HLX22	HER2	Solid Tumors	●					
	HLX55	cMET	Solid Tumors	●					
	HLX58	Claudin18.2	Solid Tumors	●					
	HLX09	CTLA4	Solid Tumors	●					
	HLX23	CD73	Solid Tumors	●					
	HLX24	CD47	Solid Tumors	●					
	HLX26	LAG3	Solid Tumors	●					
	HLX59	CD27	Solid Tumors	●					
	HLX51	OX40	Solid Tumors	●					
	HLX52	TIM-3	Solid Tumors	●					
	HLX53	TIGIT	Solid Tumors	●					
HLX63	GPC3	Solid Tumors	●						
HLX56	DR	Solid Tumors	●						
Combo Therapy	HLX04 ⁽¹³⁾ +HLX10	VEGF+PD-1	nsNSCLC	●					
	HLX04 ⁽¹³⁾ +HLX10	VEGF+PD-1	HCC	●					
	HLX07+HLX10	EGFR+PD-1	SCCHN	●					
			mESCC	●					
	HLX10 ⁽¹³⁾ +Chemo	PD-1	sqNSCLC	●					
		SCLC	●						

- Phase 2 clinical trials are not required for biosimilars.
- Our Phase 3 clinical trial for HLX01 focused on the treatment of CD20-positive diffuse large B cell lymphoma, which is the most common subtype of NHL. HLX01's reference drug, MabThera, is approved in China for three NHL subtypes (namely DLBCL, relapsed or refractory follicular central lymphoma and previously-untreated CD20-positive stage III-IV follicular lymphoma). HLX01 is also approved for these three indications.
- Our Phase 3 clinical trial for HLX02 focuses on the treatment of HER2+ metastatic breast cancer. As HLX02's reference drug, Herceptin, is approved in China for HER2+ early breast cancer, HER2+ metastatic breast cancer and HER2+ metastatic gastric cancer, our NDA in China seeks approval for all three indications for HLX02. Our commercialization partner Accord filed an MAA with the EMA for these three indications and gastroesophageal junction cancer. Subject enrollment of the Phase 3 clinical trial for HLX02 has been completed. While HLX02 is still undergoing Phase 3 clinical trial, our NDA for HLX02 was accepted by the NMPA in April 2019 and is currently under its priority review.
- Over 70 Jurisdictions and regions in Europe, MENA and CIS. Australia, New Zealand, Colombia and Malaysia.
- Our Phase 3 clinical trial for HLX03 focuses on the treatment of plaque psoriasis. As HLX03's reference drug, Humira, is approved in China for plaque psoriasis, rheumatoid arthritis and ankylosing spondylitis, we have filed for NDA approval for all three indications for HLX03. Our NDA for HLX03 was accepted by the NMPA in January 2019 and is currently under its priority review.
- Our Phase 3 clinical trial for HLX04 focuses on the treatment of mCRC. As HLX04's reference drug, Avastin, is approved in China for mCRC and unresectable, locally advanced, recurrent or metastatic nsNSCLC, we plan to seek NDA approval for both indications for HLX04. Licensed out to Shanghai Jingze.
- Includes advanced gastric cancer, gastroesophageal junction adenocarcinoma, NSCLC and mCRC.
- Considered a bio-innovative product because the originator product has not been approved for the relevant indication yet in China.
- Greater China and certain countries in Southeast, Central and South Asia.
- We do not consider HLX07, HLX10, HLX04 + HLX10 combination therapy and HLX10 + Chemo combination therapy to be our Core Products as (i) data on Phase 1 clinical trials for HLX07, HLX10 and HLX04 + HLX10 combination therapy have not become available, and (ii) data on Phase 3 clinical trials for HLX10 + Chemo, which do not require Phase 1 clinical trials, have not become available. We are also developing HLX10 to treat Hepatitis B virus.

Tumor-Specific Targets

Angiogenesis Targets

Immunotherapeutic Targets

Combo Therapy

Others

- Core products
- IND approval by Mainland CN, US & TW
- IND approval by CN & AU

Henlius Differentiation Highlights

