In-house R&D: Bio-Medicine Core Pipeline

HENLIUS 02696.HK

5 Products launched in China
- HAN LI KANG (rituximab)
- HAN QU YOU (trastuzumab)
- HAN DAY UAN (adalimumab)
- HAN BEI TAI (bevacizumab)
- HAN SI ZHUANG (serplulimab)

1 Product launched in EU
Zercepac® (trastuzumab)

13 Indications launched

2 NDAs accepted for review

12+9 Candidates / Combo Therapies under Clinical Studies

20+ Clinical studies

70+ Clinical approvals

Major therapeutic areas: oncology; autoimmune diseases; ophthalmic diseases

Commercial Capacity Currently: **24,000L**

	Products		Targets	Indications	Pre-clinical / IND / Phase 1 / Phase 2 / Phase 3 / NDA
Near Commer-cialization	HLX10(1) (serplulimab)	+chemo	PD-1	squamous non-small cell lung cancer 1L	Global multi-centre clinical study
				extensive-stage small cell lung cancer 1L	Global multi-centre clinical study
Under Clinical Studies	HLX10(1) (serplulimab) KGbio	+chemo	PD-1	metastatic esophageal squamous-cell carcinoma 1L	
				neo-/adjuvant treatment of gastric cancer	
		+HANBEITAI	PD-1+VEGF	non-squamous non-small cell lung cancer 1L	
				hepatocellular carcinoma 1L	
				metastatic colorectal cancer 1L	
		+HLX07	PD-1+EGFR	squamous cell carcinoma of the head and neck 2L	
				squamous non-small cell lung cancer 1L	
	HLX04-O(2) ESSEX 亿胜		VEGF	wet age-related macular degeneration	Global multi-centre clinical study
	HLX22 + HANQUYOU		HER2+HER2	gastric cancer	
	HLX07(3)		EGFR	solid tumours (non-small cell lung cancer, esophageal carcinoma, etc.)	
	HLX208(4)		BRAF V600E	solid tumours (metastatic colorectal cancer, non-small cell lung cancer,etc.) LCH and ECD	
	HLX11(pertuzumab)		HER2	breast cancer	
	HLX05 (cetuximab) (5) Jingze		EGFR	metastatic colorectal cancer, squamous cell carcinoma of the head and neck	
	HLX12(ramucirumab)		VEGFR2	gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer	
	HLX20(6)		PD-L1	solid tumours	
	HLX14 (denosumab)		RANKL	osteoporosis	
	HLX26		LAG-3	solid tumours, lymphomas	
	HLX35(7) BINACEA		EGFRx 4-1BB	solid tumours	
	HLX301(8)		PD-L1x TIGIT	solid tumours	
	HLX13(ipilimumab)		CTLA-4	melanoma, renal cell carcinoma and metastatic colorectal cancer	
	HLX15 (daratumumab)		CD38	multiple myeloma	
	HLX23(9)		CD73	solid tumours	

Note: last update on April 2022

(1) IND approved in China, the US, the EU, etc.
(2) IND approved in China, Australia, the US, Singapore and the EU countries, etc.
(3) IND approved in China and the US
(4) Commercialization rights in China including Hong Kong, Macau and Taiwan China were obtained
(5) Commercialization rights in China have been granted to Shanghai Jingze
(6) IND approved in China and Australia
(7)) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan China have been granted to Binacea
(8) Clinical Trial Notification has been acknowledged by the Therapeutic Goods Administration in Australia
(9) IND approved in the US

In-house R&D: Innovative Small Molecule Core Pipeline

FOCHON PHARMACEUTICALS

Pipeline candidates FCN-437 in Phase III clinical trial

FCN-159 (MEK) clinical trial in China, U.S. and Europe

The right outside of Chinese Mainland, Hong Kong SAR and Macau SAR of **FCN-338 (BCL-2)** was granted to Lilly

FOSUN ORINOVE

Pipeline candidate Orin1001 is with novel target, MOA and compound

Therapeutic Area	Project	Target/MOA	Indication	Pre-Clinical / IND / Phase 1 / Phase 2 / Phase 3 / NDA
Anti-tumor	FCN-437c	CDK4/6	Breast cancer (1L)	Approved to enter Phase 3 clinical trial by NMPA in January 2022
			Breast cancer (2L)	Approved to enter Phase 3 clinical trial by NMPA in January 2022
	SAF-189	ALK	Non-small cell lung cancer	Initiated Phase 3 clinical trial in Chinese Mainland in January 2022; approved to enter clinical trials by FDA
		ROS1	Non-small cell lung cancer	Approved to enter clinical trials by FDA
	HLX-208	BRAF V600E	Solid tumors (metastatic colorectal cancer, non-small cell lung cancer, etc.) LCH and ECD5	Approved to enter Phase 1b/Phase 2 clinical trials by NMPA in January 2022
	FCN-159	MEK	Neurofibromatosis type 1	Approved to enter clinical trials by NMPA in May 2021; approved clinical trials in the U.S. and Europe
			Low-grade glioma	
			Malignant melanoma	
	ORIN1001	-	Solid tumor	Approved Phase 1 clinical trial in the U.S.
	FCN-647	BTK	Relapsed or refractory malignant B-cell lymphoma	
	YP01001	VEGFR, etc.	Advanced solid tumor	
	FCN-338[1] Lilly	BCL-2	Hematological malignancies	Approved Phase 1 clinical trial in the U.S.
			Relapsed or refractory B-cell lymphoma	Approved to enter Phase 1 clinical trial by NMPA in October 2021
	FH-2001	FGFR/PD-L1	Advanced malignant solid tumors	Approved to enter Phase 1 clinical trial by NMPA in August 2021
	PLK1 Inhibitor	PLK1	KRAS mutations in colorectal and non-small cell lung cancer	
	CHK1 Inhibitor	CHK1	Ovarian cancer and other solid tumors	
	IRAK4/BTK Inhibitor	IRAK4/BTK	DLBCL	

Note 1: granted Lilly exclusive right to develop, manufacture and commercialize in all countries and regions excluding Chinese Mainland, Macau and Hong Kong
Note 2: last update on 28th February 2022

In-house R&D: Innovative Small Molecule Core Pipeline

Therapeutic Area	Project	Target/MOA	Indication	Pre-Clinical / IND / Phase 1 / Phase 2 / Phase 3 / NDA
Nervous System	Opicapone Tablet	COMT	Parkinson's syndromes	Launched Ongentys in Europe*
Blood System	Avatrombopag Tablet	TPO-R	Chronic idiopathic thrombocytopenic purpura	
	Tenapanor Tablet	NHE 3	End-stage Renal Disease – Hemodialysis	
Metabolism and Digestive System	Ferric Pyrophosphate Citrate	-	Iron replacement for HD patients	
	Tenapanor Tablet	NHE 3	Irritable Bowel Syndrome with Constipation	
	FCN-207	URAT1	Hyperuricemia / Gout	
	FCN-342	URAT1	Gout	Granted Phase 1 clinical trial by NMPA in November 2021
Infectious Diseases	Molnupiravir	RNA polymerase	Treatment of COVID-19	
	Paxlovid	3CL Protease	Treatment of COVID-19	
	mRNA vaccine BNT162b2	-	Immunization to prevent COVID-19	Administrated in Hong Kong, Macau and Taiwan region
	PA-824	-	XDR – Tuberculosis MDR – Tuberculosis	Launched Pretomanid in the U.S.*
Others	Fortacin spray (Lidocaine Prilocaine spray)	-	Premature ejaculation	Launched in Europe*
	ET-26	-	Anesthesia	
	ORIN1001	-	Idiopathic pulmonary fibrosis	Initiated Phase 1 clinical trial in Chinese Mainland in February 2022; Phase 1 clinical trial in the U.S.
	S1PR1 agonist	S1PR1	Inflammatory bowel disease	
	FCN-016	ROCK	Glaucoma	
	Blood coagulation factor FXLa inhibitor	FXLa	Antithrombotic	
	FH2002	Complement Factor B	IgA nephropathy and other immune abnormalities	

Note: last update on 28th February 2022