Product portfolio and pipeline

Henlius

Approved

Serplulimab [1]
PD-1
sqNSCLC, ES-SCLC, ESCC, nsqNSCLC, GC

HLX01 [2] (rituximab)
CD20
NHL, CLL, RA [3]

HLX02 [4] (trastuzumab)
HER2
BC, mGC

HLX03 [5] (adalimumab)
TNF-α
RA, AS, Ps, UV, pJIA, pediatric Ps, CD, pediatric CD

HLX04 (bevacizumab) [6]
VEGF
mCRC, NSCLC, GBM, HCC, EOC, FTC or PPC, CC

BILDYOS® (denosumab) [7]
RANKL
Osteoporosis, etc.

BILPREVDA® (denosumab) [7]
RANKL
Cancer-related bone disease, etc.

POHERDY® (pertuzumab) [8]
HER2
BC

HLX901 [9] (neratinib)
HER1/HER2/HER4
BC

Fovinaciclib [9]
CDK4/6
BC

Marketing Applications

HLX04-O [10]
VEGF
Wet AMD

HLX14 [7] (denosumab)
RANKL
Osteoporosis, Cancer-related bone disease, etc.

HLX04 (bevacizumab) [6]
VEGF
mCRC, NSCLC, GBM, HCC, CC, EOC, etc.

HLX903 [11]
EGFR-TKI
NSCLC 1L

Phase 3

Serplulimab [1] **+ Chemo**
PD-1
ES-SCLC 1L

Serplulimab [1] **+ Chemo + Radio**
PD-1
LS-SCLC 1L

Serplulimab [1] **+ bevacizumab + Chemo**
PD-1+VEGF
mCRC 1L

HLX04-O [10]
VEGF
Wet AMD

HLX22[12] (dulpatatug) **+ trastuzumab+Chemo**
HER2+HER2
GC

HLX87 [13]
HER2 ADC
BC

HLX78 [14] (lasofoxifene)
SERM
BC

Phase 2

Serplulimab [1] **+ HLX07**[15] (pimurutamab)
PD-1+EGFR
Solid tumors (sqNSCLC, etc.)

HLX07[15] (pimurutamab)
EGFR
Solid tumors (cSCC, etc.)

HLX22[12] (dulpatatug) **+ T-DXd**
HER2
HER2-low/HR+ BC

HLX43 (opucolimab pelitecan) [16]
PD-L1 ADC
Solid tumors (NSCLC, etc.)

HLX43 (opucolimab pelitecan) [16] **+ Serplulimab** [1]
PD-L1 ADC + PD-1
Solid tumors

HLX87 [13] **+ HLX22**[12] (dulpatatug)
HER2 ADC + HER2
BC 1L

HLX79 [17] **+ HLX01** (rituximab) [2]
Sialidase Fc Fusion Protein + CD20
Active Glomerular Diseases

HLX208[17]
BRAF V600E
Solid tumors

Phase 1

HLX6018
GARP/TGF-β1
IPF

HLX701 [18]
CD47-SIRPα Blockade
RAS/BRAF wild-type mCRC

HLX316
B7H3 x Sialidase
Solid tumors

HLX37
PD-L1 x VEGF BsAb
Solid tumors

HLX3901
DLL3 x DLL3 x CD3 x CD28 TetraAb
SCLC, NEC

HLX3902
STEAP1 x CD3 x CD28 TsAb
PCa

HLX48
c-MET x EGFR BsADC
NSCLC, CRC

HLX97
KAT6A/B
ERα + Breast Cancer

HLX15 [19] (daratumumab)
CD38
Multiple myeloma

HLX13 [20] (ipilimumab)
CTLA-4
Melanoma, HCC, etc.

HLX17 (pembrolizumab)
PD-1
NSCLC, TNBC, etc.

HLX319 (pertuzumab + trastuzumab, SC)
HER2+HER2
BC

HLX05-N [20] (cetuximab)
EGFR
mCRC, HNSCC

HLX18 [15] (nivolumab)
PD-1
Solid tumors (NSCLC, MEL, etc.)

IND/ Pre-IND

HLX109
IL-1R3
Autoimmune diseases (AD, Psoriasis, etc.)

HLX105
PD1 x IL2v
Solid tumors

HLX203
ActRIIA/B
lean mass management

HLX68
TL1A x IL23(p19) BsAb
IBD (UC、CD, etc.)

HLX320
TSHR x IGF1R BsAb
TED

HLX49
HER2 x HER2 ADC
Solid tumors (HER2+ BC/GC, etc.)

HLX403
CDH17 ADC
Gastrointestinal cancers

HLX41
LIV-1 ADC
BC

Innovative mAb
Innovative fusion protein
Innovative multi-specific antibody
Innovative ADC
Small molecule
Biosimilar mAb

Bridging study in U.S.
BLA under FDA review
Global MRCT
Approved in global markets

(1) Approved in 50 countries and regions, including China, the UK, Germany, India, Singapore, trade name: Hetronifly® in Europe. Business partners: KGbio/ Fosun Pharma/ Intas/ Lotus/ Abbott/ Eisai.

(2) Approved in China and multiple Latin American countries. The first biosimilar approved in China. Business partners: Fosun Pharma/ Eurofarma/ Abbott/ Boston Oncology.

(3) The first rituximab approved for the indication in China.

(4) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name in U.S.: HERCESSI™. Trade name in Europe: Zercepac®. Business partners: Accord/ Elea/ Eurofarma/ Abbott/ KGbio/ Getz Pharma.

(5) Business partners: Fosun Wanbang/ Getz Pharma.

(6) Approved in China and multiple Latin American countries. Business partners: Eurofarma.

(7) Approved in North America and Europe, Business partner: Organon. Trade name: BILDYOS® (60mg/mL), BILPREVDA® (120mg/1.7mL) in the U.S. and Europe. Marketing applications are under review in China.

(8) Approved in China, the U.S. and Europe. Trade name: POHERDY® in the U.S. and Europe. Business partner: Organon.

(9) Commercialization in China.

(10) NDA under review in China. Business partner: Essex.

(11) Exclusive commercialisation rights and development rights in Chinese Mainland and Macau.

(12) IND approvals obtained in China/ the U.S./ Japan/ the EU.

(13) The development and exclusive commercialization rights obtained in China and select ex-China markets.

(14) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China.

(15) IND approvals obtained in China/the U.S.

(16) IND approvals obtained in China/ the U.S./ Japan/ Australia/ Europe. Generic name under pINN status.

(17) Exclusive license obtained in China.

(18) Exclusive rights in China (excl. Taiwan), several countries in Southeast Asia, and other selected countries and regions; Phase 1b/2a conducting in countries such as China and the U.S.

(19) IND approvals obtained in China/the U.S. Business partner: Dr. Reddy's, etc.

(20) Business partner: Sandoz, etc.

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