Henlius Biotech
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Henlius: using a fully integrated platform to advance high-quality, affordable biologics

With its dynamic end-to-end in-house capabilities, Henlius has developed a unique pipeline of cancer and autoimmune drugs, including HLX01, a biosimilar version of MabThera. The company is now exploring the creation of further biosimilars and immuno-oncology combination therapies.

Shanghai Henlius Biotech, Inc. has progressed quickly since it began operating in 2010. Today, Henlius is a fully integrated biopharmaceutical company with dozens of clinical-phase candidates racing to join its biosimilar version of MabThera on the market.

Fosun Pharma and a team of overseas scientists founded Henlius to offer high-quality, affordable and innovative medicines to patients worldwide. Working out of the headquarters in Shanghai and R&D centers in Taipei and California, Henlius quickly moved 14 products into clinical development and won approval for the first biosimilar in China.

Henlius's rapid growth is built on a fully integrated platform that gives it innovative in-house capabilities across the entire biologics value chain, including high-titer cell line, proprietary cell culture production and continuous manufacturing process at a good manufacturing practice (GMP)-certified production plant capable of handling commercial production of multiple products.

Building a broad biologics pipeline

Henlius has used its platform to build and advance a diversified pipeline of cancer and autoimmune drugs. The power of this approach is evidenced by HLX01, Henlius's biosimilar version of MabThera. In February 2019, the Chinese regulator approved HLX01 for three indications in non-Hodgkin's lymphoma (NHL), making it the first biosimilar to come to market in the country.

The Chinese approval of HLX01 in NHL is a launchpad for Henlius. With commercial sales of HLX01 underway, Henlius is conducting a phase 3 rheumatoid arthritis trial to expand the Chinese label while bringing the MabThera copy and other products to global markets.

HLX02 exemplifies the desire of Henlius to expand globally. This biosimilar version of Herceptin (trastuzumab) was the first Chinese-developed, off-patent biologic to be approved for study in humans outside the country. In June 2019, the European regulator accepted for review the submission of the application for approval of HLX02, setting it up to potentially become the first Chinese-developed biosimilar to come to market in the European Union (Fig. 1).

Henlius's ambitions extend beyond providing affordable versions of existing therapeutic options. The biotech also offers patients new, better treatments.

In some cases, Henlius is pursuing that goal by developing biosimilars in new indications, for example, by aiming to bring HLX04, a biosimilar version of Avastin (bevacizumab), to Chinese patients with wet age-related macular degeneration or diabetic retinopathy for the first time. Additionally, Henlius is working on wholly new molecules by applying its drug discovery capabilities to targets with huge unmet medical needs.

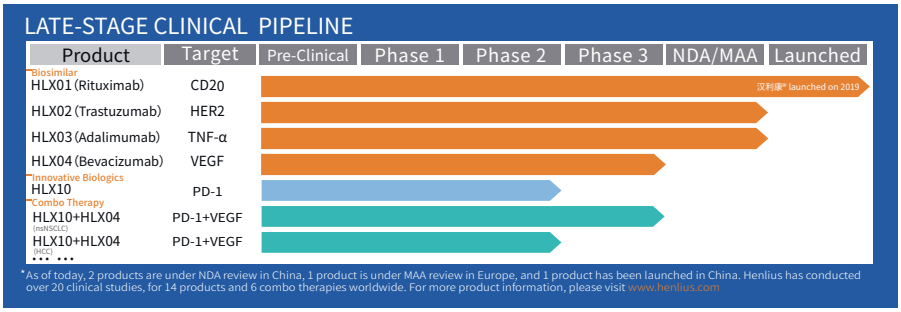

Fig. 1 | The Henlius late-stage clinical pipeline. Henlius has progressed rapidly achieving a number of milestones since its formation in 2010. HCC, hepatocellular carcinoma; NDA, new drug application; nsNSCLC, nonsquamous non-small cell lung cancer; MAA, marketing authorisation application.

Henlius's innovative clinical-phase pipeline features novel inhibitors of VEGFR2, EGFR, PD-1, PD-L1, HER2 and cMET, setting it up to treat a wide range of solid tumors. The earlier-stage pipeline features biologics against targets that include Claudin18.2, CD73, CTLA-4, TIGIT, LAG3, OX40, DR and CD47.

The breadth of Henlius's pipeline positions it to explore immuno-oncology combination therapies globally. Henlius has submitted two combination clinical programs to run global clinical trials, which pair PD-1 inhibitor HLX10 with HLX04 and HLX07, aiming to achieve synergistic effects by targeting VEGF and EGFR, respectively. A combination trial of PD-1 inhibitor HLX10 and biosimilar Avastin HLX04 has already been started. Henlius is equipped to evaluate some of the most promising combinations in the whole cancer field, such as the pairing of a checkpoint inhibitor and an anti-immunosuppressive CD47 molecule.

Henlius is also interested in emerging modalities such as bispecific antibodies, cancer vaccines and oncolytic viruses, positioning itself to stay at the cutting edge of oncology research.

Establishing commercial capabilities

Henlius's global R&D and regulatory registration capabilities equip it to take drugs to market in countries around the world. With three more therapies set to join HLX01 on the Chinese market in the near term, Henlius is building a dedicated marketing, sales and market access team.

The management team at Henlius has identified an independent commercialization strategy as the best way to win market share and create value within China. That strategy leverages the support of Fosun, Henlius's parent company and a major commercial-stage player in the Chinese market.

Henlius is concurrently pursuing a different strategy outside China. In these markets, Henlius partners with global pharmaceutical companies. Henlius has partnered with companies including Accord Healthcare, Biosidus S.A., Cipla and The Jacobson Group to bring its therapeutics to patients across the Americas, Asia and Europe.

In September, Henlius struck another collaboration agreement with a total milestone payment of up to $692 million to illustrate its global strategy for PD-1. The agreement gives PT Kalbe Genexine Biologics (KGBio) the exclusive right to develop and commercialize HLX10 in the Philippines, Indonesia and a total of ten Southeast Asian countries.

The breadth of Henlius's pipeline means there are more partnerships to come. Having established an innovative, fully integrated platform to build a broad pipeline of biologics, Henlius is well equipped to bring a stream of biological products to the market. Now, Henlius is seeking partners to help it get products to patients outside China.

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