

Making biologic medicines more accessible

Global biopharmaceutical company Henlius aims to greatly improve patient well-being with **AFFORDABLE AND INNOVATIVE BIOLOGIC MEDICINES**

Patients with cancer or autoimmune diseases often deal with long periods of debilitating symptoms with the conditions sometimes life-threatening. Even those fortunate enough to find an effective treatment may face the hurdle of high costs.

Recognizing these challenges, and personally experiencing the loss of a loved one to cancer, two biologists and Fosun Pharma founded Henlius in 2010 with a vision of offering high-quality, affordable and innovative biologic medicines with a focus on cancer, autoimmune diseases and ophthalmic diseases.

AN ALTERNATIVE TO COSTLY BIOLOGICS

Henlius has made great advances in the field of biosimilars. These, as the name suggests, are designed to be very similar to brand-name drugs in their clinical effect, but are lower in cost. They can be made available when pharmaceutical companies' exclusive patents on drugs expire.

Biosimilars are not to be confused with generic drugs, which are also marketed as an affordable alternative to brand-name drugs. Biosimilars

are modelled after drugs that are biological, also known as biologics, meaning they use living organisms as ingredients. Generic drugs, however, are identical copies of synthetic drugs that are created using a chemical process.

The complexity and costs of developing biosimilars are much higher than developing generic drugs, explains Jason Zhu, chief medical officer and senior vice president of Henlius. "Biosimilars are comprised of large complex molecules, while generic drugs consist of small molecules," says Zhu. "To develop biosimilars typically takes around 7-8 years and US\$100-300 million, while to develop generic drugs usually takes about 2-3 years and US\$2-3 million.

Biosimilars are rising in demand, notes Zhu, despite the higher costs and technology requirements involved in their development. This is because biologics are increasingly proving to be effective treatments for certain diseases. Also, the patents of many biologics are due to expire, making it an opportune time for the development and introduction of biosimilars to offset drug prices.



Henlius has built an integrated biopharmaceutical platform with high efficiency and innovation embedded throughout the product life cycle.

For example, consider therapeutics for HER2 positive breast cancer. "In the past, HER2 positive breast cancer was almost untreatable, and patients suffered a lot," says Zhu. "The introduction of biologic trastuzumab in 1998 provided a life-saving alternative for the treatment of this deadly disease."

However, trastuzumab is a costly drug, so this is where biosimilars can fill the gap, says Zhu.

"With biosimilars, we can bring down the price of such drugs significantly as the market will no longer be exclusively dominated by the branded drug. This benefits patients the most," he adds.

There are now several biosimilars for trastuzumab in the market, including one launched by Henlius and approved by both the European Commission and China's National Medical Products Administration (NMPA) in 2020. The biosimilar has undergone a global Phase III clinical study and been demonstrated as highly similar to trastuzumab in terms of quality, safety and efficacy. In addition to China, the biosimilar has been launched in European countries including France, Germany, Hungary, Ireland, Italy, Spain and Switzerland.

Besides trastuzumab, Henlius has also launched two

other biosimilars, including one for rituximab in 2019 and another for adalimumab in 2020. Zhu explains that the Rituximab biosimilar is the first biosimilar to come to market in the country.

More than 70,000 Chinese patients have benefited from biosimilars produced by Henlius.

THINK BIG AND GO GLOBAL

Going forward, Zhu says, Henlius hopes to expand its global reach and help more patients tackle life-threatening diseases. The company has built an integrated biopharmaceutical platform with high

efficiency and innovation embedded throughout the product life cycle, including R&D, manufacturing and commercialization. Meanwhile, the company has invested globally in talent, including research centres in both California and Shanghai and development teams in the US and China. On this basis, Henlius has joined forces to upgrade marketed products like bevacizumab by optimizing the prescription, specifications and production processes.

In 2022, Henlius plans to launch Serplulimab, an immunotherapy drug that targets the PD-1 receptor. "One of the indications of



Henlius has research centres in California and Shanghai and development teams in the US and China.



Xuhui Manufacturing Facility is certificated by China and the EU GMP.

Serplulimab is to help patients with high levels of MSI, a cancer biomarker. This means the drug can target many types of cancers, such as endometrial cancer, colorectal cancer and gastric cancer, potentially benefiting a large population," says Zhu.

Other indications for Serplulimab include the treatment of non-small cell lung cancer and small cell lung cancer. Zhu says Henlius has already submitted applications to China's NMPA for the first two indications. He outlines plans to submit applications, leveraging the clinical data from global multi-centre clinical trials, to authorities abroad,

such as the US Food and Drug Administration (FDA), and hopes to launch this drug in overseas markets.

"What's really exciting is that as we receive more clinical data for Serplulimab, we are gaining confidence that we own one of the best molecules in the PD-1 class," he says. "In addition, Henlius has a proven manufacturing capability for reliable product supply. Every day, we are determined to serve more patients in need." ■



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