ADVERTISEMENT FEATURE

An original force in biosimilars

A Shanghai-based joint venture is the national leader in DEVELOPING ANTIBODY-BASED BIOSIMILAR AND BIOLOGIC PRODUCTS, providing patients with quality, affordable therapeutics.

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From monoclonal antibodies (mAb) to recombinant proteins, biologics offer great potential for disease treatment, including for cancer, diabetes, and autoimmune diseases. Produced from living cells or microorganisms, they are, however, much more complex and expensive to make than chemical pharmaceuticals. Replicating original biologics offers a cost-effective solution. The market for 'biosimilars' is booming in China and across the world.

Shanghai Henlius Biotech has developed China's first approved biosimilar drug, HLX01, to be used primarily for treating non-Hodgkin's lymphoma, a type of blood cancer.

Co-founded by Fosun Pharma and a group of overseas scientists in 2010, this joint venture focuses on the development, production and commercialization of mAb biosimilar drugs and novel mAbs. Here, two of its founders, Scott Liu and Weidong Jiang, tell of their ambition to provide affordable treatment for patients.

Liu: When Weidong and I started the company in the US, we planned to come back to China, which has the largest market for biological drugs. Yet back then, China had none of its own antibody drugs. The few on the market were all imported and too expensive for patients. With years of experience working on biologics in leading international pharmaceutical companies in the US, we saw the great potential of biologics and were eager to bring novel treatment options to Chinese patients. I also had personal reasons for wanting to work on affordable biological drugs.

Jiang: As with Scott, my personal experience led me back to China to work on biologics. I had family members who died of cancer due to a lack of effective treatment. I knew antibody drugs would offer them hope, but they were not available in China back then. So our initial ambition for Henlius was to improve patient lives by providing them innovative and affordable medicines. We put quality first, and also value innovation and speed, as these are closely connected.

Liu: It is the emphasis on speed that made us choose biosimilars as a forerunner. As developing biologics is very time-consuming and complicated, by developing proven originals we can significantly shorten the R&D period, and bring bioequivalent treatment to market much faster.

However, this is no simple copy-and-paste work. Biologics are structurally complex large molecules produced in living cells and more difficult to characterize than chemically synthesized small-molecule drugs. The biological processes are inherently variable and highly sensitive to manufacturing conditions. Changes to any step of the production process may alter the structure, biological activity, effectiveness and safety of the biologics. It takes good techniques to keep the bioequivalence.

Jiang: The advantages of biosimilars lie in the proven safety and efficacy of the original biologics. We can have the same target antigens, so there is relatively lower risk, and greater potential for success. In line with our development strategy, we can help patients get effective treatments sooner. Improved access may bring clinical benefits, as earlier and more appropriate uses of biologic treatments are associated with better outcomes. After all, achieving optimal treatment for patients is a shared goal for us and the physicians.

Liu: Developing biosimilars in China was challenging a decade ago. The European Medicines Agency (EMA) was the first to introduce guidelines for biosimilars in 2005, and the US FDA launched relevant regulations in 2010. The China National Medicinal Products Administration (NMPA; formerly named China FDA) did not publish its first technical guidelines for biosimilar development until 2015, which broadly followed similar principles as the EMA and the FDA.

Moreover, biologics and biosimilars are more complex and challenging to manufacture than small molecules, requiring process innovations. The biological development did not start blooming here until large groups of overseas Chinese professionals with sophisticated techniques started flowing back. And only with correct techniques and well trained talents, biopharma companies can develop quality biologics in line with the global standards.

Jiang: As Scott said, we had nothing but the EU and FDA guidelines to follow for the development of HLX01 in 2011. There were also no competent CROs to work with. As the regulatory body might not have the necessary knowledge to review and evaluate biosimilars, industry pioneers, including Henlius, worked closely with China NMPA to explore and define the pathway for developing biosimilars in China. We all learned a lot through this process.

Liu: Our advantage is the technology we harness, which enables us to produce quality products effectively and at lower cost. For instance, the production of biologics demands maintaining the biological activity of proteins. The cell culture media we developed meets this requirement, and also helps cut down the cost. The R&D platform we created integrates mAb screening, cell line development, cell culturing, downstream protein purification, and biological preparation, putting us in a leading position. Backed by an international GMP standard facility, we are equipped with advanced single-use bioreactors to ensure high-quality manufacturing.

Jiang: At Henlius, we emphasize quality and doing things in the right way, as this ensures efficiency and saves time by avoiding unnecessary mistakes. Leveraging the best practices from leading international pharmaceutical companies, our effective project management system and R&D procedure, with some adaptations, will help ensure quality and speed.

Liu: We also have talented research and management professionals, most of whom returned from overseas with great education qualifications or credentials, and industry experiences. We attract them not just because of our advanced technology and infrastructure, but also due to our strong sense of mission. We also emphasize ethics, and try to create a supportive environment to encourage initiative and innovation.

Jiang: With a focus on innovation, we are also developing follow-ups and bio-novels. Until now, we have completed the IND/CTA submission of 13 products and two combinations with 23 indications, mainly covering cancer and autoimmune diseases. Seven of these are bio-novel products, including four entering the stage of clinical trials. Also in our pipeline is the combination therapy in immuno-oncology, combining PD-1/PD-L1 inhibitors with other monoclonal antibodies to enhance the effectiveness of cancer immunotherapy. ■

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