Generating biosimilar therapeutic drugs through innovative technology and operational excellence

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Shanghai Henlius Biotech, Inc. is a leading biopharmaceutical company in China determined to develop and deliver high quality, affordable and innovative drugs to patients worldwide. Founded in 2010 and headquartered in Shanghai, Henlius has established and continues to expand its comprehensive product pipeline of biosimilars and bio-innovative medicines to treat tumours and autoimmune diseases.

Dr Scott Liu and Dr Weidong Jiang, co-founders of the company, each possess more than 25 years of hands-on experience in developing therapeutic drugs and have held leadership positions in research and development (R&D), manufacturing and quality management at top international biopharmaceutical companies. Henlius has built a high-calibre team of experts with rich experience in developing and commercialising drug candidates. The team is inspired by the company's vision and the science-oriented, practical and meritocratic corporate culture.

Henlius has developed an efficient fully integrated platform with innovative in-house capabilities throughout the entire biologics value chain.

AN INTEGRATED AND PRODUCTIVE GLOBAL RESEARCH AND DEVELOPMENT PLATFORM

Henlius has built an integrated and efficient global R&D platform across three R&D facilities located in Shanghai and Taipei, China and in California, United States (US). The company has more than 210 R&D employees led by industry veterans. The global R&D platform, with extensive in-house R&D resources and end-to-end capabilities, enables Henlius to closely control the entire product development process, from discovery and process development to manufacturing and post-marketing clinical follow-up.

GLOBAL REGULATORY REGISTRATION AND CLINICAL DEVELOPMENT CAPABILITY

Henlius had designed and conducted more than 15 clinical trials with 10 concurrent clinical trials in 6 different countries and areas worldwide. This achievement demonstrates the company's strong capability to efficiently and successfully manage a large number of clinical trials simultaneously, including multiple late-stage clinical trials. All stages of clinical trials are managed by a team with more than 100 clinical and medical staff, many of whom have extensive global experience and knowledge of good clinical practices.

COMPREHENSIVE QUALITY MANAGEMENT SYSTEMS

Henlius has established a comprehensive quality management system (QMS) that meets the quality standards of the US, European Union (EU) and China, supported by 118 quality assurance and quality control employees, laying the foundation for regulatory approval and commercialization of their products worldwide. Managed by a team of overseas-trained experts in pharmaceutical quality management, Henlius' Xuhui facility and accompanying QMS have passed the on-site inspection conducted by an EU-qualified person.

COMMERCIAL-SCALE AND COST-EFFICIENT MANUFACTURING FACILITIES

Henlius has completed the construction of its first facility with a 13,000-litre capacity for antibody drug pilot production and commercialization located in the Shanghai Caohejing Hi-Tech Park. The manufacturing facility has been built in accordance with international good manufacturing practice standards and uses international advanced equipment such as single-use bioreactors to keep up with Henlius' new product launches.

STRONG GLOBAL COMMERCIALIZATION CAPABILITIES

The company has assembled a dedicated marketing team with extensive industry experience, which will be further expanded. Henlius has also initiated strategic commercialization collaborations with global leading pharmaceutical companies including Accord, Cipla, Biosidus and Jacobson Medical, covering 82 countries and regions globally, which will enable it to expeditiously capture market share through the established capabilities and resources of the partners.

Through its efficient and innovative in-house capabilities, Henlius has developed a diversified, advanced and high-quality drug pipeline of more than 20 in-house biosimilar candidates and bio-innovative drugs, with significant potential for a variety of PD-1/PD-L1-based immuno-oncology combination therapies.

As of March 2019, Henlius has completed IND/CTA filings of 13 products and 2 combination therapy with 23 indications and obtained 29 successful IND/CTA approvals (19 approvals from China; 3 from the US; 3 from Taiwan; each 1 from the EU, Ukraine, Philippines and Australia). HLX01 (rituximab injection), the first product to be researched and developed by Henlius, has been granted approval by the China National Medical Products Administration (NMPA) as the first approved biosimilar in China. Moreover, HLX03 (adalimumab injection) has its new drug application under review by the NMPA.

Looking forward, Henlius will continue to pursue technical innovation and operation excellence in drug discovery and development to improve patients' lives by providing high-quality affordable treatments. Henlius strives to be the most admired biotech company in the world.