NEWS RELEASE

Phase 3 Comparative Clinical Study of Prolia ® and Xgeva ® (denosumab) Biosimilar Candidate HLX14 Met Primary Endpoints

4/8/2024

SHANGHAI, China & JERSEY CITY, N.J.--(BUSINESS WIRE)-- Shanghai Henlius Biotech, Inc. (2696.HK) and Organon (NYSE: OGN) announced that the phase 3 comparative clinical trial for the investigational Prolia® and Xgeva® (denosumab) biosimilar HLX14 met the primary endpoints. In 2022, Henlius entered into a license and supply agreement with Organon for the exclusive commercialization rights to two biosimilar candidates, including HLX14. The agreement covers markets such as the United States, the European Union, and Canada. An exception to the agreement is China.

The randomized, double-blind, international multicenter, parallel-controlled phase 3 clinical study (**NCT05352516**) aimed to compare the efficacy, safety, tolerability, and immunogenicity of HLX14 with EU-sourced reference denosumab (Prolia®) in postmenopausal women with osteoporosis at high risk for fracture. Eligible patients were randomised at a 1:1 ratio to receive subcutaneous injection of 60 mg of HLX14 or reference denosumab (Prolia®) every six months. The primary efficacy endpoint of this study was the percentage change in bone mineral density (BMD) at the lumbar spine from baseline to Week 52 (D365) assessed by central imaging. The primary pharmacodynamic endpoint was the area under the effect–time curve for percentage change of serum type I collagen C-telopeptide (s-CTX) from baseline to Week 26 (D183) (AUEC0–26W). The primary endpoints of this study were met.

Denosumab has been approved in various countries and regions under different trade names for a range of different indications such as for the treatment of osteoporosis in postmenopausal women at high risk for fracture,

among others.

About Henlius

Henlius (2696.HK) is a global biopharmaceutical company with the vision to offer high-quality, affordable, and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases, and ophthalmic diseases. Up to date, 5 products have been launched in China, 2 have been approved for marketing in overseas markets, 19 indications are approved worldwide, and 7 marketing applications have been accepted for review in China, the U.S., and the EU, respectively. Since its inception in 2010, Henlius has built an integrated biopharmaceutical platform with core capabilities of high-efficiency and innovation embedded throughout the whole product life cycle including R&D, manufacturing and commercialization. It has established global innovation centers and Shanghai-based manufacturing facilities in line with global Good Manufacturing Practice (GMP), including Xuhui Facility and Songjiang First Plant, both certificated by China and the EU GMP.

Henlius has pro-actively built a diversified and high-quality product pipeline covering over 50 molecules and has continued to explore immuno-oncology combination therapies with proprietary HANSIZHUANG (anti-PD-1 mAb) as backbone. Apart from the launched products HANLIKANG (rituximab), the first China-developed biosimilar, HANQUYOU (trastuzumab for injection, trade name in Europe: Zercepac®), the first China-developed mAb biosimilar approved both in China and Europe, HANDAYUAN (adalimumab) and HANBEITAI (bevacizumab), the innovative product HANSIZHUANG has been approved by the NMPA for the treatment of MSI-H solid tumours, squamous non-small cell lung cancer (sqNSCLC) and extensive-stage small cell lung cancer (ES-SCLC), and esophageal squamous cell carcinoma (ESCC), making it the world's first anti-PD-1 mAb for the first-line treatment of SCLC. What's more, Henlius has conducted over 30 clinical studies for 16 products, expanding its presence in major markets as well as emerging markets.

To learn more about Henlius, visit **www.henlius.com/en/** or connect with us on LinkedIn at **https://www.linkedin.com/company/henlius/**.

About Organon

Organon is a global healthcare company formed to focus on improving the health of women throughout their lives. Organon offers more than 60 medicines and products in women's health in addition to a growing biosimilars business and a large franchise of established medicines across a range of therapeutic areas. Organon's existing products produce strong cash flows that support investments in innovation and future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, visit **http://www.organon.com** and connect with us on **LinkedIn**, **Instagram**, **X (formerly known as Twitter)** and **Facebook**.

Cautionary Note Regarding Forward-Looking Statements

Some statements and disclosures in this press release are “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements about expectations regarding Organon’s license and supply agreement with Henlius. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may," “expects,” “intends,” “anticipates,” “plans,” “believes,” “seeks,” “estimates,” “will,” or words of similar meaning. These forward-looking statements are based on Organon’s current plans and expectations and are subject to a number of risks and uncertainties that could cause Organon’s plans and expectations, including actual results, to differ materially from the forward-looking statements.

Risks and uncertainties that may affect Organon’s future results include, but are not limited to, our inability to successfully commercialize products in our biosimilars portfolio, the performance, operations and regulatory compliance of Henlius and its suppliers, efficacy, safety, or other quality concerns with respect to marketed products, including market actions such as recalls, withdrawals, or declining sales; political and social pressures or regulatory developments, that adversely impact demand for, availability of, or patient access to Organon’s products; general economic factors, including recessionary pressures, interest rate and currency exchange rate fluctuations; general industry conditions and competition; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Organon’s ability to accurately predict its future financial results and performance; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of Organon’s patents and other protections for innovative products; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Organon undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Organon’s filings with the Securities and Exchange

Commission ("SEC"), including Organon's most recent Annual Report on Form 10-K and subsequent SEC filings, available at the SEC's Internet site (**www.sec.gov**).

Organon Media Contacts:

Karissa Peer

(614) 314-8094

Hannah Silver

(917) 509-8864

Organon Investor Contacts:

Jennifer Halchak

(201) 275-2711

Alex Arzeno

(203) 550-3972

Henlius Media Contacts

Bella Zhou

wenting_zhou@henlius.com

Janice Han

jiayi_han@henlius.com

Source: Organon & Co.