Life is Rare

October 1, 2025
JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Announces Licensing Agreement with Menagen to Commercialize Agalsidase Beta BS I.V. Infusion [JCR] Across Nine MENAT Markets

Hyogo, Japan – October 1, 2025 – JCR Pharmaceuticals Co., Ltd. (TSE 4552; "JCR"), a global specialty biopharmaceutical company dedicated to developing therapies for rare and genetic diseases, today announced an exclusive licensing agreement with Menagen Pharmaceutical Industries LLC (headquartered in Oman, CEO: Saif Al Hasani, "Menagen") to seek local marketing authorizations and to commercialize Agalsidase Beta BS I.V. Infusion [JCR] (the "product") upon approval across nine MENAT markets. The product is a recombinant enzyme replacement therapy (ERT) for Fabry disease currently marketed in Japan.

Under the agreement, Menagen will file local applications in the licensed territories across the MENAT markets, leveraging the product's Japanese approval. The licensed territories include: the Kingdom of Saudi Arabia, United Arab Emirates, the Sultanate of Oman, the State of Kuwait, the State of Qatar, the Kingdom of Bahrain, the Republic of Türkiye, the Republic of Iraq, and the Arab Republic of Egypt. Following local approvals, JCR will supply the product, and Menagen will lead commercialization in the region.

"This agreement allows us to broaden access to our Fabry therapy beyond Japan," said Shin Ashida, Chairman, President and CEO of JCR Pharmaceuticals. "By working with Menagen, we aim to improve treatment options for people living with Fabry disease across these markets."

Developed by JCR, the product is a biosimilar ERT for Fabry disease and is the first lysosomal storage disorder (LSD) enzyme therapy manufactured in Japan using serum-free cell culture. JCR launched the product in Japan in November 2018 and, since 2022, has been marketed by Sumitomo Pharma Co., Ltd. under a commercialization agreement. Domestic net sales in FY2024 were approximately JPY 1.1 billion.

JCR does not expect a material impact on FY2025 consolidated results.

About Fabry Disease

Fabry disease is a rare, X-linked inherited lysosomal storage disorder caused by deficiency or reduced activity of α-galactosidase A. Enzyme deficiency leads to accumulation of globotriaosylceramide (GL-3) and globotriaosylsphingosine (Lyso-GL-3) within lysosomes, resulting in multisystem involvement and a broad spectrum of clinical manifestations.

References: Burlina A, et al. An expert consensus on the recommendations for the use of biomarkers in Fabry disease. Mol Genet Metab. 2023; 139(2): 107585.

About JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceutical company that develops treatments that go beyond rare diseases to solve the world's most complex healthcare challenges. We continue to build upon our 50-year legacy in Japan while expanding our global footprint into the U.S., Europe, and Latin America. We improve patients' lives by applying our scientific expertise and unique technologies to research, develop, and deliver next-generation therapies. Our approved products in Japan include therapies for the treatment of growth disorder, MPS II (Hunter syndrome), Fabry disease, acute graft-versus host disease, and renal anemia. Our investigational products in development worldwide are aimed at treating rare diseases including MPS I (Hurler, Hurler-Scheie and Scheie syndrome), MPS II, MPS IIIA and B (Sanfilippo syndrome type A and B), and more. Our core values – Putting people first, Forging our own path, Always advancing, and Committed to excellence – mean that the work we do benefits all our stakeholders, including partners, patients and employees. We strive to expand the possibilities for patients while accelerating medical advancement at a global level. For more information, please visit JCR's global website: https://jcrpharm.com/.

Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control. Forward-looking statements often contain words such as "believe," "estimate," "anticipate," "intend," "plan," "will," "would," "target" and similar references to future periods. All forward-looking statements regarding our plans, outlook, strategy and future business, financial performance and financial condition are based on judgments derived from the information available to us at this time. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but are not limited to, a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors' pricing and product strategies, a decline in marketing capabilities relating to our products, manufacturing difficulties or delays, an infringement of our intellectual property rights, an adverse court decision in a significant lawsuit and regulatory actions. This document involves information on pharmaceutical products (including those under development). However, it is not intended for advertising or providing medical advice. Furthermore, it is intended to provide information on our company and businesses and not to solicit investment in securities we issue. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

Contact:

Investors & Media:
JCR Pharmaceuticals Co., Ltd.
Corporate Communications
ir-info@jp.jcrpharm.com

###