News Release

November 26, 2021

Succession of Manufacturing and Marketing Approval and Marketing Rights of REPLAGAL® 3.5 mg for Fabry Disease, an α-Galactosidase Enzyme IV Infusion

- ***Takeda Is to Succeed the Manufacturing and Marketing Approval and the Marketing Rights of REPLAGAL® 3.5 mg for Fabry Disease from Sumitomo Dainippon Pharma on February 15, 2022***

Takeda Pharmaceutical Company Limited (Head Office: Chuo-ku, Osaka, Japan; President, CEO and Representative Director: Christoph Webber) (hereinafter, Takeda) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Chuo-ku, Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) (hereinafter, Sumitomo Dainippon Pharma) announced today that Takeda will succeed the manufacturing and marketing approval and the marketing rights of REPLAGAL® 3.5 mg for Fabry disease, an α-galactosidase enzyme intravenous (IV) infusion (hereinafter, REPLAGAL®), from Sumitomo Dainippon Pharma as of February 15, 2022.

REPLAGAL® is used for the treatment of Fabry disease and was launched in Japan by Sumitomo Dainippon Pharma in February 2007. Currently, Sumitomo Dainippon Pharma holds its manufacturing and marketing approval in the Japanese market based on a license agreement with Takeda Pharmaceuticals America Inc., a group company of Takeda. Upon expiration of the license agreement, Takeda will take over the manufacturing and marketing approval of REPLAGAL®.

As of February 14, 2022, Sumitomo Dainippon Pharma will terminate the marketing of REPLAGAL® and related information provision activities, and on February 15, 2022, Takeda will take over its marketing and information provision activities.

The two companies will work to smooth out the succession and transfer.

<u>About Fabry Disease</u>

Fabry disease is caused by a genetic deficiency or decreased activity of the enzyme “α-galactosidase A (α-GAL A),” one of the hydrolases (hydrolytic enzymes) in intracellular lysosomes.
This enzyme has the function of decomposing a glycolipid called “GL-3” or “Gb3 (globotriaosylceramide, also known as ceramide trihexoside, CTH).” However, if its activity is insufficient, undecomposed GL-3 gradually accumulates in cells, tissues, and organs throughout the body. When the accumulated GL-3 exceeds a certain level, various symptoms start to appear, including neurological symptoms such as pain, angiokeratoma, corneal opacity, cardiac dysfunction, and renal dysfunction.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE: TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in healthcare in approximately 80 countries.
For more information, visit https://www.takeda.com.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Co., Ltd. defines it corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide."
By channeling our efforts into the research and development of new drugs, we aim to realize our mission and provide innovative and effective pharmaceutical solutions not only to people in Japan but also around the world. Sumitomo Dainippon Pharma's goal is to create innovative pharmaceutical products in the focus research areas of psychiatry and neurology, oncology, and regenerative medicine/cell therapy.
For details, please visit: https://www.ds-pharma.com/

Disclaimer

The pharmaceutical information included in this news release is intended merely to disclose the management information of the two companies and is not intended to promote or advertise any pharmaceutical products, including those under development.

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