



March 1, 2022

JCR Pharmaceuticals Co., Ltd.  
Sumitomo Dainippon Pharma Co., Ltd.

**JCR and Sumitomo Dainippon Pharma Enter into Marketing Alliance for Agalsidase Beta BS I.V. Infusion [JCR], for Treatment of Fabry Disease in Japan**

JCR Pharmaceuticals Co., Ltd. (Head Office: Ashiya, Hyogo; Chairman and President: Shin Ashida; “JCR”) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka; Representative Director, President and CEO: Hiroshi Nomura; “Sumitomo Dainippon Pharma”) announced today that they have concluded an agreement regarding marketing alliance for Agalsidase Beta BS I.V. Infusion 5 mg [JCR] and Agalsidase Beta BS I.V. Infusion 35 mg [JCR] (recombinant protein) (hereinafter collectively referred to as the “Product”), which are currently being sold by JCR for the treatment of Fabry disease.

Based on the agreement, from April 1, 2022, Sumitomo Dainippon Pharma will exclusively engage in information dissemination activities on the Product to healthcare professionals. Also, Sumitomo Dainippon Pharma will exclusively commence to market and distribute the Product within the second quarter of fiscal 2022 by receiving supply of it from JCR.

Sumitomo Dainippon Pharma will make an upfront payment under the terms of the agreement to JCR and may make sales milestone payments depending on achievement of sales targets.

This Product is a biosimilar of a therapeutic enzyme (recombinant human agalsidase beta) for Fabry disease. It was developed by JCR and is the first therapeutic enzyme for lysosomal storage diseases in Japan manufactured using serum-free culture technology. JCR has been selling this Product since November 2018 and in the third quarter of fiscal 2021, cumulative sales reached approximately 500 million yen.

Sumitomo Dainippon Pharma has positioned therapeutic areas with high unmet medical needs requiring a high level of specialization as a specialty area to focus its Japan business, which include Fabry disease and other rare diseases. The company has long-standing experiences in this area.

This marketing alliance between the two companies will further enhance both partner’s contribution to the treatment of Fabry disease patients.

Reference

About Fabry disease

Fabry disease is a hereditary lysosomal storage disorder linked to the X-chromosome, in which the lysosomal enzyme  $\alpha$ -galactosidase A ( $\alpha$ -GLA) is congenitally deficient or reduced in activity. The resulting accumulation of the glycolipid substrate globotriaosylceramide (GL-3 or Gb3) causes Fabry disease symptoms in various parts of the body.

### About Agalsidase Beta BS I.V. Infusion 5 mg [JCR] and 35 mg [JCR]

This Product was launched by JCR in November 2018 as the first biosimilar of a therapeutic enzyme for Fabry disease in Japan manufactured using serum-free culture technology. Phase I and Phase II/III clinical studies demonstrated equivalence and comparability regarding efficacy and safety with the original product, Agalsidase Beta (recombinant protein)\*.

\* Mol Genet Metab. 2020 Jul; 130 (3): 215-24

### About JCR Pharmaceuticals Co., Ltd.

JCR is a biopharmaceutical specialty pharma which is engaged in research, development, manufacture, and market of pharmaceuticals based on regenerative medicine, genetic recombination, and gene therapy technologies that have pioneered the era under our corporate philosophy of "Contributing towards people's healthcare through pharmaceutical products."

In the arena of rare diseases, which has been JCR's target since its establishment in 1975, JCR has been working on proprietary technology developments and creation of products in a manner to be "one step ahead" of competitors at all times. JCR aims to create sustainable values for patients with various diseases.

Our core values – reliability, confidence, and persistence – benefit all our stakeholders, including employees, partners, and patients. Together we soar.

For more information, please visit <https://www.jcrpharm.co.jp/en/site/en/>.

### About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Co., Ltd. defines its 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, Sumitomo Dainippon Pharma aims 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 positions Psychiatry & Neurology area, Diabetes area, and Specialty area (an area with high unmet medical needs in which intensive specialization is required) as Focus Areas for the Japan business.

For more information, please visit <https://www.ds-pharma.com/>.

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