

## Press Release

### **Astellas Submits Supplemental New Drug Application for Approval of Additional Indication of Selective SGLT2 Inhibitor Ipragliflozin L-Proline for Patients with Type 1 Diabetes Mellitus in Japan**

Tokyo and City, January 11, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas" ) and Kotobuki Pharmaceutical Co., Ltd. (President and CEO; Hiroshi Tomiyama, "Kotobuki") today announced that Astellas submitted an application for the additional indication of the selective SGLT2 inhibitor Ipragliflozin L-Proline (generic name, brand name: "Suglat® Tablets, development code: ASP1941, "Ipragliflozin") for the treatment of type 1 diabetes mellitus in Japan.

Type 1 diabetes mellitus is a disease with insulin deficiency that occurs when the  $\beta$  cells in the pancreas, which secrete insulin, are destroyed through immune system. It has been estimated that around 10 million people in Japan are very likely to have diabetes<sup>1</sup>. It was estimated that type 1 diabetes mellitus account for around 6% of patients with diabetes<sup>2</sup>.

Ipragliflozin is a selective SGLT2 (Sodium-Glucose Co-transporter 2) inhibitor discovered through a research collaboration and is being jointly developed with Kotobuki. SGLTs are membrane proteins exist on the cell surface and transfer glucose into cells. SGLT2 is one subtype of SGLTs that plays a key role in the reuptake of glucose in the proximal tubule of the kidneys. By selectively inhibiting SGLT2, Ipragliflozin suppresses the reuptake of glucose and reduces blood glucose levels.

Ipragliflozin received marketing approval for the indication of type 2 diabetes under the brand name Suglat® Tablets in January 2014 and has been on the market since April 2014.

Through the application for the indication, Astellas expects to provide a new treatment option for patients with type 1 diabetes mellitus whose glycemic control is inadequate and enhance its contribution to the treatment of diabetes.

The submission of the application for an approval has no impact on Astellas' consolidated financial forecasts for the fiscal year 2017 ending March 31, 2018.

(1) Overview of “National Health and Nutrition Survey” Findings in 2016, Ministry of Health, Labour and Welfare.

(2) Japan Diabetes Complication and its Prevention (JDCP) Prospective Study 2015,

#### **About Astellas**

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

#### **About Kotobuki**

Kotobuki Pharmaceutical Co., Ltd., based in Nagano, Japan, is a company dedicates its efforts to research and development of innovative drugs and to provide generic drugs. We put a priority on Diabetes/Nephrology, Gastroenterology, Dyslipidemia, Oncology and Immunology as focused therapeutic areas in our research. We continuously pursue high level of creativity in drug discovery, quality of products and morality for contributing to higher level of quality of life and healthy life expectancy of patients.

For more information, please visit our website at <https://ssl.kotobuki-pharm.co.jp/en/>

#### **Cautionary Notes (Astellas)**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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