Press Release

Approval of Suglat® Tablets, Selective SGLT2 Inhibitor, for Additional Indication of type 1 diabetes mellitus and Additional dosage and administration in Japan

Tokyo, December 21, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) and Kotobuki Pharmaceutical Co., Ltd. (President and CEO; Hiroshi Tomiyama, “Kotobuki”) today announced that approval of selective SGLT2 inhibitor Suglat® Tablets (generic name: Ipragliflozin L-Proline , development code: ASP1941, "Suglat®") for the additional indication of type 1 diabetes mellitus and the additional dosage and administration has been obtained in Japan. Suglat® received marketing approval for the indication of type 2 diabetes mellitus in January 2014 and has been on the market since April 2014 in Japan.

Suglat® is a selective SGLT2 (Sodium-Glucose Co-transporter 2) inhibitor discovered through a research collaboration 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, Suglat® suppresses the reuptake of glucose and reduces blood glucose levels.

Type 1 diabetes is a disease with insulin deficiency that occurs when the β 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[1]. It was estimated that type 1 diabetes account for around 6% of patients with diabetes[2].

Astellas will continue contributing to the treatment of diabetes through providing new treatment options for patients with type 1 diabetes mellitus who have inadequate glycemic control with insulin.

Astellas reflected the impact from this launch in its financial forecasts of the current fiscal year ending March 31, 2019.

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

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

Product overview (with additional underlined areas)

Trade name	Suglat® 25mg Suglat® 50mg
Generic name	Ipragliflozin L-Proline
Indication	Type 2 Diabetes mellitus Type 1 Diabetes mellitus
Dosage and administration	Type 2 diabetes mellitus For adults, the usual oral dosage is 50 mg as ipragliflozin once daily before or after breakfast. In the case of inadequate efficacy, the dose may be increased to 100 mg once daily while careful monitoring of the patient’s conditions. Type 1 diabetes mellitus For adults, the usual oral dosage is 50 mg as ipragliflozin once daily before or after breakfast, coadministered with insulin prep-arations. In the case of inadequate efficacy, the dose may be in-creased to 100 mg once daily while careful monitoring of the patient’s conditions.
Date of approval	December 21, 2018

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. 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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