



March 23, 2018

To whom it may concern:

MSD K.K.  
Astellas Pharma Inc.

**SUJANU<sup>®</sup> Combination Tablets combining type-2 diabetes drugs  
receive marketing approval in Japan**  
- Drug combining selective DPP-4 inhibitor and selective SGLT2 inhibitor -

Tokyo, March 23, 2018 -MSD K.K. (President: Jannie Oosthuizen; “MSD”) and Astellas Pharma Inc. (President and CEO; Yoshihiko Hatanaka; “Astellas”) today announced that MSD received the marketing approval of SUJANU<sup>®</sup> Combination Tablets, co-developed by the two companies, for the treatment of type-2 diabetes from the Ministry of Health, Labor and Welfare. SUJANU<sup>®</sup> Combination Tablets combine the DPP-4 inhibitor sitagliptin phosphate hydrate (trade name: JANUVIA<sup>®</sup> Tablets) and the SGLT2 inhibitor ipragliflozin L-Proline (trade name: Suglat<sup>®</sup> Tablets) in Japan.

SUJANU<sup>®</sup> Combination Tablets are once-daily oral tablets containing active ingredients of JANUVIA<sup>®</sup> Tablets, the first selective DPP-4 inhibitor in Japan manufactured and marketed by MSD, and Suglat<sup>®</sup> Tablets, the first selective SGLT2 inhibitor in Japan manufactured and marketed by Astellas. SUJANU<sup>®</sup> Combination Tablets selectively inhibit DPP-4 and increase the active incretin levels, thus demonstrating glucose-dependent glucose-lowering effect, while also selectively inhibiting SGLT2 and blocking renal glucose reuptake, thus demonstrating non-insulin-dependent glucose-lowering effect. With the two different mechanisms of action, the combination drug is expected to improve patients’ adherence and help them maintain and improve long-term stable control of blood glucose levels.

SUJANU<sup>®</sup> Combination Tablets are shown to be biologically equivalent with combined use of sitagliptin and ipragliflozin. Phase 3 studies have been conducted in Japan including a study that evaluates additional sitagliptin administration in patients who are using ipragliflozin, a study that evaluates additional ipragliflozin administration in patients using sitagliptin, and a long-term combination study that evaluates additional ipragliflozin administration in patients using sitagliptin. These studies have demonstrated efficacy and safety of SUJANU<sup>®</sup> Combination Tablets.

SUJANU<sup>®</sup> Combination Tablets will be manufactured and marketed by MSD and distributed by Astellas. MSD, Astellas, and Kotobuki Pharmaceutical Co., Ltd. (based on sales collaboration with Astellas) will jointly provide medical institutions with information.

MSD and Astellas expect that SUJANU® Combination Tablets will be a new option for the treatment of type-2 diabetes and further contribute to the treatment of diabetes.

### **Product overview**

Trade name	SUJANU® Combination Tablets
Generic names	Sitagliptin phosphate hydrate Ipragliflozin L-Proline
Indication	Type-2 diabetes Only when considered appropriate to treat with combined use of sitagliptin phosphate hydrate and ipragliflozin L-Proline
Dosage and administration	Normally to adult, one tablet (50 mg/50 mg as sitagliptin/ipragliflozin) once daily orally before or after breakfast
Date of approval	March 23, 2018

### **About MSD**

For more than a century, MSD, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for the world's most challenging diseases. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.msd.co.jp](http://www.msd.co.jp) and connect with us on [Facebook](#) or [YouTube](#).

### **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>.

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### **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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