



MSD K.K.  
Astellas Pharma Inc.

## **MSD submits application for approval of type-2 diabetes drug combining selective DPP-4 inhibitor and selective SGLT2 inhibitor**

Tokyo, May 19, 2017 -MSD K.K. (President: Jannie Oosthuizen; “MSD”) and Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka; “Astellas”) today announced that MSD has submitted an application for marketing approval of a combination drug of the DPP-4 inhibitor sitagliptin phosphate hydrate (brand name: JANUVIA<sup>®</sup> Tablets) and the SGLT2 inhibitor ipragliflozin L-Proline (brand name: Suglat<sup>®</sup> Tablets) for the treatment of type-2 diabetes in Japan.

JANUVIA<sup>®</sup> Tablet is the first selective DPP-4 inhibitor in Japan manufactured and marketed by MSD. This once-daily inhibitor selectively inhibits DPP-4 and increases the active incretin levels, thus demonstrating glucose-dependent glucose-lowering effect. Suglat<sup>®</sup> Tablet is the first selective SGLT2 inhibitor in Japan manufactured and marketed by Astellas. With once-daily administration, it selectively inhibits SGLT2 and blocks renal glucose reuptake, thus demonstrating non-insulin-dependent glucose-lowering effect. The combination of these two drugs with different mechanisms of action for the treatment of type-2 diabetes is expected to reduce patients’ burden of taking drugs and improve their adherence. In a clinical study conducted to support this application, the drug has shown efficacy, safety and tolerability.

MSD and Astellas look forward to further contributing to the treatment of diabetes by offering a new treatment option for type-2 diabetes patients who have difficulty controlling blood sugar levels with monotherapy.

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### **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 [www.astellas.com/en](http://www.astellas.com/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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