Astellas Submits New Drug Application for Extended-Release Tablets of Quetiapine Fumarate in Japan

Tokyo, August 9, 2016 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced that it submitted a new drug application to the Ministry of Health, Labour and Welfare in Japan for extended-release tablets of quetiapine fumarate (generic name, Code No.: FK949E) for the indication of improvement of depressive symptoms associated with bipolar disorder. Astellas has a license agreement with AstraZeneca UK Ltd. (LSE: AZN, headquarters: the United Kingdom, CEO: Pascal Soriot) that provides Astellas exclusive rights to develop and commercialize extended-release tablets of quetiapine fumarate in Japan.

This application is based primarily on the results of a Phase-III clinical trial consisting of a placebo-controlled, double-blind, comparative study and an extension study, to confirm the efficacy and safety of extended-release tablets of quetiapine fumarate, administered orally once daily to Japanese patients diagnosed with bipolar depression. The program started following a development request from the Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs.

Astellas expects this new drug application will provide an additional therapeutic option to patients diagnosed with bipolar depression, and thus will make a contribution to treatment of neuropsychiatric disorders.

This submission in Japan has no impact on Astellas' financial results for the fiscal year ending March 31, 2017.

Cautionary Notes

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.

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.

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