Press Release

U.S. FDA Grants Fast Track Designation to Astellas for Development of Gilteritinib in Relapsed or Refractory Acute Myeloid Leukemia

TOKYO – October 11, 2017 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of gilteritinib for adult patients with FLT3 mutation-positive (FLT3+) relapsed or refractory acute myeloid leukemia (AML). Fast Track designation is designed to facilitate the development, and expedite the FDA review, of drugs to treat serious and life-threatening conditions so that, if approved, the compounds can reach the market expeditiously.

"Mutations of FLT3 in AML are associated with a poor prognosis and we are committed to working with the FDA to meet the requirements of the expedited review process," said Steven Benner, M.D., senior vice president and global therapeutic area head, oncology development, Astellas. "We are pleased that the FDA has acknowledged the urgent need for new therapies for FLT3+ AML patients, which may allow for an expedited review process for gilteritinib."

Fast Track designation for gilteritinib may allow for more frequent meetings and correspondence with the FDA, consideration for Priority Review if supported by clinical data, and Rolling Review, which means Astellas can submit completed sections of its New Drug Application (NDA) for review by the FDA rather than waiting until every section of the application is completed before the NDA can be reviewed.

AML is a cancer that impacts the blood and bone marrow and is most commonly experienced in older adults. According to the American Cancer Society, in 2016 there were approximately 21,000 new patients diagnosed with AML in the United States and about 10,000 cases resulted in death.

Gilteritinib is an investigational compound that has demonstrated inhibitory activity against FLT3 internal tandem duplication (ITD) as well as FLT3 tyrosine kinase domain (TKD), two common types of FLT3 mutations that are seen in approximately one-third of patients with AML. Further, gilteritinib has also demonstrated inhibition of AXL, which is reported to be associated with therapeutic resistance.

Astellas is currently investigating gilteritinib in various AML patient populations through four ongoing Phase 3 trials, including the registrational ADMIRAL trial in relapsed/refractory FLT3+ AML.

The safety and efficacy of the agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for the uses being investigated. Information about pharmaceutical products (including products currently

in development) which is included in this press release are not intended to constitute an advertisement or medical advice.

About Gilteritinib
Gilteritinib was discovered through a research collaboration with Kotobuki Pharmaceutical Co., Ltd., and Astellas has exclusive global rights to develop, manufacture and potentially commercialize gilteritinib. Astellas internally classifies highly prioritized research projects as “Fast Track,” meaning research and development time is minimized through the focused investment of both capabilities and resources. Gilteritinib was designated as our first Fast Track project.

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.

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.

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