Astellas Contacts
For Media
Tyler Marciniak
(224) 205-6340
tyler.marciniak@astellas.com

For Investors
So Sekine
(847) 224-9557
sou.sekine@astellas.com

U.S. FDA Grants Orphan-Drug Designation to Astellas for Development of FLT3 Inhibitor Gilteritinib in Acute Myeloid Leukemia

TOKYO – July 20, 2017 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced today that the U.S. Food and Drug Administration (FDA) granted orphan-drug designation to gilteritinib in patients with acute myeloid leukemia (AML). The Orphan Drug Designation program assigns status to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of diseases or disorders that affect fewer than 200,000 people in the United States.

"Fewer than 10,000 Americans will be diagnosed with FLT3 mutation-positive AML this year and while that may be a small percentage of the overall population, it is an important group of patients who are deserving of potential new treatments," said Steven Benner, M.D., senior vice president and global therapeutic area head, oncology development, Astellas. "We are grateful to the FDA for acknowledging the unique needs of rare diseases and for providing a path forward for gilteritinib in supporting these patients."

Gilteritinib is a receptor tyrosine kinase inhibitor of FLT3 and AXL, which are involved in the growth of cancer cells. Gilteritinib has demonstrated inhibitory activity against FLT3 internal tandem duplication (ITD) as well as tyrosine kinase domain (TKD), two common types of FLT3 mutations that are seen in up to one third of patients with AML. AML is a cancer that impacts the blood and bone marrow and most commonly experienced in older adults. According to the American Cancer Society, in 2016 there were an estimated 21,000 new cases of AML diagnosed in the United States and about 10,600 cases resulted in death.

Astellas is currently investigating gilteritinib in various AML patient populations through several planned and already initiated 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 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.

###