Press Release

Astellas to Present New Data Exploring Gilteritinib in Newly Diagnosed Acute Myeloid Leukemia (AML) Patients at the 2017 American Society of Hematology Annual Meeting (ASH)

– A breadth of abstracts highlighting the acute myeloid leukemia treatment landscape, healthcare resource use and cost of care to be presented during oral and poster sessions –

TOKYO – November 28, 2017 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced new data in acute myeloid leukemia (AML) research, including preliminary results from a Phase 1 study of the investigational agent gilteritinib in combination with induction and consolidation chemotherapy in patients with newly diagnosed AML, it will present at the 2017 American Society of Hematology (ASH) Annual Meeting.

The wide selection of abstracts showcases the company's full-scale development program across the FLT3 mutation-positive (FLT3mut+) AML care continuum—from newly-diagnosed to relapsed or refractory patients.

"This research further shows FLT3 mutations are one of the most commonly occurring mutations in AML, and we are pleased to be continuing our commitment to addressing the needs of AML patients," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "Further, we're pleased to showcase additional data that examines the cost of care as well as healthcare utilization in the current treatment of FLT3mut+ AML."

The following abstract will be presented during an oral presentation session:

Title: Preliminary Results from a Phase 1 Study of Gilteritinib in Combination with Induction and Consolidation Chemotherapy in Subjects With Newly Diagnosed Acute Myeloid Leukemia (AML) (Abstract 722)

Presenter: Keith W. Pratz, M.D., John Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore

- Session Date/Time: Monday, December 11, 3:00 p.m. EST
- Location: Building B, Level 5, Murphy BR 1-2

In addition to the oral presentation, Astellas will present the following five abstracts during poster sessions:

Title: Treatment Patterns and Healthcare Resource Utilization in Patients with FLT3-mut and FLT3-wt Acute Myeloid Leukemia: A Multi-country Medical Chart Study (Abstract 2186)

Lead Author: James D. Griffin, M.D.

- Session Date/Time: Saturday, December 9, 5:30-7:30 p.m. EST
- Location: Building A, Level 1, Hall A2

Title: Comparative Assessment of FLT3 Variant Allele Frequency by Capillary Electrophoresis and Next-Generation Sequencing in FLT3^{mut+} Patients with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) who Received Gilteritinib Therapy (Abstract 1411)

Lead Author: Catherine C. Smith, M.D.

- Session Date/Time: Saturday, December 9, 5:30-7:30 p.m. EST
- Location: Building A, Level 1, Hall A2

Title: Real-World Occurrence of Symptoms and Toxicities and Associated Cost Implications in Acute Myeloid Leukemia (AML) Treatment Episodes: A Retrospective Database Analysis in the U.S. (Abstract 2118)

Lead Author: Bhavik Pandya, Pharm.D.

- Session Date/Time: Saturday, December 9, 5:30-7:30 p.m. EST
- Location: Building A, Level 1, Hall A2

Title: Evaluation of the Impact of Minimal Residual Disease, *FLT3* Allelic Ratio, and *FLT3* Mutation Status on Overall Survival in FLT3 Mutation-Positive Patients with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) in the CHRYSALIS Phase 1/2 Study (Abstract 2705)

Lead Author: Mark J. Levis, M.D., Ph.D.

- Session Date/Time: Sunday, December 10, 6:00-8:00 p.m. EST
- Location: Building A, Level 1, Hall A2

Title: Economic Burden of Treatment Episodes in Acute Myeloid Leukemia (AML) Patients in the U.S.: A Retrospective Analysis of a Commercial Payer Database (Abstract 4694)

Lead Author: Bruno C. Medeiros, M.D.

- Session Date/Time: Monday, December 11, 6:00-8:00 p.m. EST
- Location: Building A, Level 1, Hall A2

About Gilteritinib
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 all patients with AML. Further, gilteritinib has also demonstrated inhibition of the AXL receptor in AML cell lines, which has been reported to be associated with

therapeutic resistance. Astellas is currently investigating gilteritinib in various AML patient populations through several Phase 3 trials. Visit AstellasAMLTrials.com to learn more about ongoing gilteritinib clinical trials.

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. Gilteritinib has been granted Orphan Drug designation and Fast Track designation by the U.S. FDA, and SAKIGAKE designation by the Japan Ministry of Health, Labor and Welfare.

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 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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