Press Release

Astellas to Present New Data on Gilteritinib in Multiple Populations of FLT3 Mutation-Positive Acute Myeloid Leukemia (AML) Patients at the 2018 American Society of Hematology (ASH) Annual Meeting

- Abstracts include updated results from Phase 1 study of gilteritinib in patients with newly diagnosed AML -

TOKYO – November 19, 2018 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D. "Astellas") today announced it will present new data in Acute Myeloid Leukemia (AML) research at the 60th American Society of Hematology (ASH) Annual Meeting, taking place December 1-4, 2018 in San Diego, California. Among the data being presented are updated results from a Phase 1 study of gilteritinib in combination with induction and consolidation chemotherapy in patients with newly diagnosed AML.

At ASH, collaborating researchers from renowned academic medical centers will present data exploring the use of gilteritinib to treat patients across the FLT3 mutation-positive (FLT3mut+) AML care continuum—from newly diagnosed to relapsed or refractory patients—and on healthcare resource utilization in the current treatment of FLT3mut+ AML. Additionally, Astellas will sponsor two sessions in ASH's Friday Satellite Symposia program prior to the meeting.

"Patients with this life-threatening disease have long had limited treatment options. Developing new therapies that help address unmet medical needs and provide physicians with new tools to treat patients in multiple stages of the FLT3mut+ AML journey is our priority," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "We're pleased to present new data at ASH examining the potential for gilteritinib to treat diverse groups of FLT3mut+ AML patients, and to share research on healthcare resource utilization among this patient population."

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

Title: Updated 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 564)

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

- Session Date/Time: Monday, December 3, 8:15 a.m. PST
- Location: Manchester Grand Hyatt, Seaport Ballroom F

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

Title: Impact of Minimal Residual Disease and Achievement of Complete Remission/Complete Remission With Partial Hematologic Recovery (CR/CRh) on Overall Survival Following Treatment With Gilteritinib in Patients With Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) With *FLT3* Mutations (Abstract 1458)

Lead Author: Mark J. Levis, M.D., Ph.D., John Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore

- Session Date/Time: Saturday, December 1, 6:15 p.m. PST
- Location: San Diego Convention Center, Hall GH

Title: Multicenter, Open-Label, 3-Arm Study of Gilteritinib, Gilteritinib Plus Azacitidine, or Azacitidine Alone in Newly Diagnosed FLT3 Mutated (FLT3mut+) Acute Myeloid Leukemia (AML) Patients Ineligible for Intensive Induction Chemotherapy: Findings From the Safety Cohort (Abstract 2376)

Lead Author: Jordi Esteve, M.D. Ph.D., Hospital Clínic de Barcelona, Barcelona, Spain

- Session Date/Time: Sunday, December 2, 6:00 p.m. PST
- Location: San Diego Convention Center, Hall GH

Title: Treatment Patterns and Healthcare Resource Utilization (HRU) in Patients With Relapsed/Refractory (R/R) *FLT3*-Mutated (*FLT3*^{mut}) and *FLT3*-Wild Type (*FLT3*^{wt}) Acute Myeloid Leukemia (AML): A Multi-Country Medical Chart Study (Abstract 4824)

Presenter: James D. Griffin, M.D., Dana-Farber Cancer Institute, Boston

- Session Date/Time: Monday, December 3, 6:00 p.m. PST
- Location: San Diego Convention Center, Hall GH

Astellas will sponsor the following symposia during the pre-meeting Friday Satellite Symposia (FSS):

Title: Moving Toward Precision Therapy for Patients with AML: Clinical Challenges and Future Directions

- Session Date/Time: Friday, November 30, 12:30 p.m. PST
- Location: Marriott, San Diego Ballroom

Title: Novel Therapies for AML: Expanding Future Options

- Session Date/Time: Friday, November 30, 12:30 p.m. PST
- Location: San Diego Convention Center, Room 1AB

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 patients with AML.Further, gilteritinib has also demonstrated inhibition of

the AXL receptor in AML cell lines. Astellas is currently investigating gilteritinib in various AML patient populations through several additional 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.

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. For more information, please visit our website at https://www.astellas.com/us/.

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.

Contacts for inquiries or additional information:
United States:
Media inquiries: Marjorie Moeling
TEL: +1-224-205-5205 E-MAIL: marjorie.moeling@astellas.com

Japan:
Media and Investor Relations inquiries:
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473