Press Release

Astellas to Present Research on FLT3 Mutation-Positive Acute Myeloid Leukemia – from Diagnosis to Relapse – at 2021 American Society of Hematology Annual Meeting

- *Four AML oral presentations are among highest number of Astellas-sponsored ASH abstracts to date*
- *Full results of Phase 3 LACEWING, COMMODORE trials will be presented*
- *Oral presentation explores potential sickle cell disease treatment pathway*

TOKYO, Dec. 1, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced the presentation of new investigational data in acute myeloid leukemia (AML) and sickle cell disease at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition, taking place December 11-14, in Atlanta, Ga. Astellas' largest ASH showing to date includes 11 AML abstracts, including four oral presentations.

"Research being presented at this year's ASH meeting investigates gilteritinib across the FLT3-mutation-positive AML disease continuum," said Ahsan Arozullah, M.D., M.P.H., Vice President, Medical Sciences-Oncology, Astellas. "Several presentations highlight data for gilteritinib in a wide range of patients – from newly diagnosed to relapsed or refractory patients, and in varying combination regimens."

Presentations will include results from two Phase 3 trials: three abstracts from LACEWING, a clinical trial which included patients with newly diagnosed FLT3 mutation-positive (FLT3mut+) AML who were ineligible for first-line intensive induction chemotherapy; and one from COMMODORE, a trial of gilteritinib versus salvage chemotherapy in patients with FLT3mut+ relapsed or refractory AML conducted in China, Malaysia, Thailand, Singapore, and Russia.

Astellas will also present research based on patients' perspectives of AML symptoms, life impact and treatment. "A deeper understanding of patient experiences is vital as we seek better treatment approaches in all stages of AML," said Erhan Berrak, M.D., Vice President of Medical Affairs, Oncology, Astellas. "For example, one study to be presented at this year's ASH meeting investigated the patient experience after a stem-cell transplant, shedding light on both symptoms and emotional impact, which can inform efforts to better serve patients post-transplant."

In addition, Astellas plans to present new preclinical data on sickle cell disease (SCD) for ASP8731, a novel BACH1 inhibitor that potentially induces fetal hemoglobin (HbF). The data show potential to increase expression of antioxidant and HbF genes and reduce SCD-related

pathophysiology. This may result in the reduction of hemolysis, inflammation, and vaso-occlusive pain crises in patients living with the condition.

“We are pleased to have the opportunity to present our preclinical data supporting further development of ASP8731, our BACH1 inhibitor,” said Itsuro Nagase, Ph.D., D.V.M., Vice President and Primary Focus Lead, Mitochondrial Biology, Astellas. “These data further support our focus on mitochondrial disease research and the advances we are making across the Astellas research pipeline to develop novel therapies for patients with unmet medical needs.”

Oral Presentations

Title: Symptoms and Impacts Reported by Patients with Acute Myeloid Leukemia (AML) in Remission Post-Stem Cell Transplant (Abstract 278).

- Presenting author: Thomas Leblanc, M.D., M.A., Department of Medicine, Duke University School of Medicine, Durham, N.C., USA
- Session Date/Time: Saturday, Dec. 11, 2:15 p.m. ET

Title: Phase 3, Open-Label, Randomized Study of Gilteritinib and Azacitidine vs Azacitidine for Newly Diagnosed FLT3-Mutated Acute Myeloid Leukemia in Patients Ineligible for Intensive Induction Chemotherapy (LACEWING) (Abstract 700).

- Presenting author: Eunice S. Wang, M.D., Department of Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, N.Y., USA
- Session Date/Time: Monday, Dec. 13, 3:30 p.m. ET

Title: Gilteritinib Versus Salvage Chemotherapy for Relapsed/Refractory FLT3-Mutated Acute Myeloid Leukemia: A Phase 3, Randomized, Multicenter, Open-Label Trial in Asia (COMMODORE) (Abstract 695).

- Presenting author: Jianxiang Wang, M.D., State Key Laboratory of Experimental Hematology, Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Tianjin, China
- Session Date/Time: Monday, Dec. 13, 3:45 p.m. ET

Title: Venetoclax in Combination with Gilteritinib Demonstrates Molecular Clearance of FLT3 Mutation in Relapsed/Refractory FLT3-mutated Acute Myeloid Leukemia (Supported by AbbVie, Astellas and Genentech) (Abstract 691).

- Presenting author: Naval Daver, M.D., Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, Texas, USA
- Session Date/Time: Monday, Dec. 13, 2:45 p.m. ET

Title: ML-0207/ASP8731: A Novel BACH1 Inhibitor That Induces Fetal Hemoglobin in Treatment of Sickle Cell Disease (Abstract 854).

- Presenting author: Greg Vercellotti, MD, Division of Hematology, Oncology and Transplantation, University of Minnesota, Minneapolis, Minn., USA
- Session Date/Time: Monday, Dec. 13, 6:30 p.m. ET

Poster Presentations

Title: A Phase 1, Dose-Escalation Study of Gilteritinib Combined with Chemotherapy in Patients Aged 6 Months to <21 Years with FLT3 Internal Tandem Duplication-Positive Relapsed or Refractory AML (Abstract 2315).

- Presenting author: Philip Connor, M.B.B.S., Department of Pediatric Hematology/Oncology, Noah's Ark Children's Hospital for Wales, Cardiff, Wales, UK
- Session Date/Time: Sunday, Dec. 12, 6-8 p.m. ET

Title: Impact of FLT3 Mutation Clearance After Front-Line Treatment with Gilteritinib Plus Azacitidine, or Gilteritinib or Azacitidine Alone in Patients with Newly Diagnosed Acute Myeloid Leukemia Ineligible for Intensive Chemotherapy: Results from the Phase 3 LACEWING Trial (Abstract 3445).

- Presenting author: Eunice S. Wang, M.D., Department of Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, N.Y., USA
- Session Date/Time: Monday, Dec. 13, 6-8 p.m. ET

Title: Patient Reported Outcomes in Patients with Newly Diagnosed FLT3mut+ Acute Myeloid Leukemia Ineligible for Intensive Induction Chemotherapy From LACEWING: A Randomized Phase 3 Trial of Gilteritinib and Azacitidine Versus Azacitidine Alone (Abstract 3058).

- Presenting author: Eunice S. Wang, M.D., Department of Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, N.Y., USA
- Session Date/Time: Sunday, Dec. 12, 6-8 p.m. ET

Title: First Salvage Therapy for Relapsed or Refractory Acute Myeloid Leukemia: Associated Health Care Resource Use and Costs (Abstract 1936).

- Presenting author: Lori Muffly, M.D., M.S., Division of Blood and Marrow Transplantation, Stanford University, Stanford, Calif., USA
- Session Date/Time: Saturday, Dec. 11, 5:30-7:30 p.m. ET

Title: Gilteritinib Can Be Safely Combined with Atezolizumab for The Treatment of Relapsed or Refractory FLT3-Mutated AML: Results of a Phase 1 Study (Abstract 2343).

- Presenting author: Jessica K. Altman, M.D., Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Feinberg School of Medicine, Chicago, Ill., USA
- Session Date/Time: Sunday, Dec. 12, 6-8 p.m. ET

Title: Patient and Physician Preferences for Treatment of Newly Diagnosed Acute Myeloid Leukemia (AML) in Patients Not Candidates for Intensive Chemotherapy (Abstract 4047).

- Presenting author: Mo Zhou, Ph.D., Analysis Group, Boston, Mass., USA
- Session Date/Time: Monday, Dec. 13, 6-8 p.m. ET

Online-Only Publication

Title: Real-World Use of FLT3 Tyrosine Kinase Inhibitors in Patients with Relapsed/Refractory FLT3 Mutation-Positive Acute Myeloid Leukemia in the United States (Abstract 5033).

About Acute Myeloid Leukemia (AML)

Acute myeloid leukemia (AML) is an aggressive cancer that affects the bone marrow and blood, and its incidence increases with age.[1,2] Of patients newly diagnosed with AML and tested for FLT3 mutations, approximately one-third have an alteration to the FLT3 gene. FLT3-ITD mutations have been associated with worsened disease-free survival and overall survival, and a higher risk of getting the disease more than once. FLT3 mutation status can change over the course of AML treatment, even after relapse.[3-6]

About Gilteritinib
Gilteritinib is an FMS-like tyrosine kinase 3 (FLT3) inhibitor with demonstrated activity against FLT3-ITD, a common driver mutation that presents with a high disease burden and poor prognosis, and FLT3-TKD mutations.[7] It was discovered through a research collaboration with Kotobuki Pharmaceutical Co., Ltd., and Astellas has exclusive global development, commercialization and manufacturing rights to gilteritinib.[8]

United States Gilteritinib Full Prescribing Information
For more information about gilteritinib please see the U.S. Full Prescribing Information at:
https://astellas.us/docs/xospata.pdf

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at https://www.astellas.com/en.

ASP8731 and Primary Focus Mitochondria Biology
The mission of Primary Focus Mitochondria Biology – part of Astellas' Focus Area Approach – is to become the global leader in discovering, developing and bringing to market mitochondria biology-based medicine that provides clear value for patients, clinicians and healthcare systems. The BACH1 inhibitor ASP8731, which can modulate mitochondrial biology, was discovered by researchers at Mitobridge and tested in models of sickle cell disease at the University of Minnesota. Mitobridge was acquired by Astellas in 2018.

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.

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