Press Release

New Research Reflects Astellas' Commitment to Acute Myeloid Leukemia at EHA 2021 Virtual Congress

Eight abstracts cover FLT3 mutation-positive AML, patient treatment preferences and utilization in hard-to-treat blood cancer

TOKYO, June 8, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced the presentation of new data in acute myeloid leukemia (AML) at the European Hematology Association (EHA) virtual congress, taking place June 9-17.

Eight Astellas-sponsored abstracts focused on patients with AML are being presented, comprising two oral presentations, four posters and two online-only abstract publications.

"We're pleased to present new investigational research at EHA 2021 that examines how patients and healthcare providers value different treatment approaches in AML," said Erhan Berrak, M.D., Vice President of Medical Affairs, Oncology, Astellas. "For example, one oral presentation sheds light on patients' preferences for treatment, which may help to inform decisions of healthcare professionals when considering a plan for treatment after hematopoietic stem cell transplantation."

"Clinical trial results to be presented reflect our deep commitment to AML research, where we are investigating gilteritinib as monotherapy or in combination with other treatments, and across the range of patients with FLT3 mutation-positive AML, including patients whose AML is newly diagnosed or relapsed or refractory," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head, Astellas.

Oral Presentations
Oral presentations are available online from Friday, June 11 at 9 a.m. CEST, when all prerecorded presentations will be published on the virtual congress platform.

Title: Patient and Physician Preferences for Post–Hematopoietic Stem Cell Transplantation Maintenance Treatment of Acute Myeloid Leukemia (Abstract S313)

- Presenting author: Manasee V. Shah, Astellas Pharma Inc., Northbrook, Ill., USA

Title: Efficacy and Safety of Venetoclax in Combination with Gilteritinib for Relapsed/Refractory FLT3-Mutated Acute Myeloid Leukemia: Updated Analyses of a Phase 1b Study (Supported by AbbVie, Astellas and Genentech) (Abstract S135)

- Presenting author: Jessica K. Altman, Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, Ill., USA

E-Poster Presentations
E-poster presentations are available from Friday, June 11 at 9 a.m. CEST, when the e-posters are published on the virtual congress platform.

Title: Follow-up of Patients with FLT3-Mutated Relapsed or Refractory Acute Myeloid Leukemia in the Phase 3 ADMIRAL Trial (Abstract EP438)
- Presenting author: Mark J. Levis, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, Md., USA

Title: Clinical Outcomes in Patients with Relapsed/Refractory Acute Myeloid Leukemia Treated with Gilteritinib Who Received Prior Midostaurin or Sorafenib (Abstract EP448)
- Presenting author: Alexander E. Perl, Abramson Comprehensive Cancer Center, University of Pennsylvania, Philadelphia, Pa., USA

Title: Outcomes in Gilteritinib-Treated FLT3-Mutated R/R AML Patients Who Underwent Transplantation (Abstract EP441)
- Presenting author: Alexander E. Perl, Abramson Comprehensive Cancer Center, University of Pennsylvania, Philadelphia, Pa., USA

Title: A Phase 1 Study of Gilteritinib in Combination with Induction and Consolidation Chemotherapy in Patients with Newly Diagnosed AML: Final Results Update (Abstract EP437)
- Presenting author: Keith W. Pratz, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, Md., USA

Online-only abstract publications
Online-only abstracts are available via the virtual congress platform.

Title: Retrospective Assessment of Treatment Patterns and Resource Utilization for Patients Newly Diagnosed with Acute Myeloid Leukemia in Canada, UK, France, Germany, Italy, and Spain (Abstract PB1390)

Title: Frequency of FLT3-ITD and FLT3-TKD Mutations in Patients with Acute Myeloid Leukemia: A Systematic Literature Review and Meta-Analysis (Abstract PB1405)

The EHA 2021 virtual congress abstracts are available in the EHA Library.

About Acute Myeloid Leukemia (AML)
Acute myeloid leukemia (AML) is a type of cancer that affects the bone marrow and blood. It is deemed “acute,” meaning that this type of leukemia can progress quickly.[1] In the European Union, the incidence rate of AML is 3.7 per 100,000 per year, resulting in an estimated 16,800 individuals diagnosed.[2]

About Gilteritinib
Gilteritinib was discovered through a research collaboration with Kotobuki Pharmaceutical Co., Ltd., and Astellas has exclusive global rights to develop, manufacture and commercialize gilteritinib. Gilteritinib is available as XOSPATA™ in the U.S., Japan, China and selected European countries, among others, for the treatment of adult patients who have relapsed or refractory FLT3mut+ AML.[3,4,5] 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 burden and poor prognosis, and FLT3-TKD mutations.[6]

European Union Important Safety Information
For important Safety Information for gilteritinib please see the full Summary of Product Characteristics at: https://www.ema.europa.eu/en/documents/product-information/xospata-epar-product-information_en.pdf

United States Important Safety Information
For important Safety Information for gilteritinib please see Important Safety Information at:
https://www.xospatahcp.com/important-safety-information

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.

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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References

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[2] Visser O. et al. Incidence, survival and prevalence of myeloid malignancies in Europe. Eur J Cancer (2012) 48, 3257–3266.
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[4] Japan Pharmaceutical and Medical Devices Agency (PMDA). New Drug approvals, April 2018 - March 2019. Available at: https://www.pmda.go.jp/files/000233675.pdf. Last accessed June 2, 2021.
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[6] Ramos NR, et al. Current Approaches in the Treatment of Relapsed and Refractory Acute Myeloid Leukemia. J Clin Med. 2015;4:665-695.