Press Release

Astellas and Hovon Confirm Phase 3 Study Did not Meet its Primary Endpoint of Overall Survival in Patients with Newly Diagnosed *FLT3*m+ AML

TOKYO AND ROTTERDAM, March 9, 2026 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") and HOVON Foundation (Rotterdam, The Netherlands) today announced that the Phase 3 HOVON 156 / AMLSG 28-18 / PASHA study investigating XOSPATA™ (gilteritinib) versus midostaurin-based treatment in patients with newly diagnosed *FLT3*-mutated acute myeloid leukemia *(FLT3*m+ AML*)* eligible for intensive chemotherapy did not meet its primary endpoint of overall survival (OS) at the primary analysis.

While the study did not meet its primary endpoint of OS, gilteritinib showed a comparable OS benefit to midostaurin-based treatment in newly diagnosed *FLT3*m+ AML. The rates of treatment emergent adverse events and grade 3 or higher adverse events were similar between both treatment arms. Astellas and HOVON will complete a full evaluation of the data from HOVON 156 / AMLSG 28-18 / PASHA, including secondary endpoints, subgroup analysis and the safety of gilteritinib in combination with chemotherapy, and work with investigators on the future dissemination of the results.

Moitreyee Chatterjee-Kishore, PhD, MBA, Head of Oncology Development, Astellas
"Whilst we are disappointed that the study did not meet its primary endpoint, we extend our thanks to all study participants for their contributions. Astellas remains committed to advancing *FLT3*-targeted research to improve outcomes across the AML treatment landscape."

Marleen C. Breems-de Ridder, PhD, CEO, HOVON Foundation
"Even when research findings are disappointing, we know that they provide important contributions to our collective understanding. We will continue our mission to conduct rigorous clinical research to improve outcomes for patients with hematologic diseases. HOVON and AMLSG would like to express their gratitude to participating patients and all investigators and collaborative groups conducting this collaborative academic study."

Astellas expects this result to have a minor impact on its financial results for the fiscal year ending March 31, 2026.

Gilteritinib is a *FLT3* inhibitor with demonstrated activity against *FLT3*-ITD, a common driver mutation that presents with a high disease burden and poor prognosis, and *FLT3*-tyrosine kinase domain (TKD) mutations.[1] Gilteritinib is available as XOSPATA™ across the world, including in the U.S., Japan, China and multiple European countries for the treatment of adult patients who have relapsed or refractory *FLT3*+ AML.

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.[1] It was discovered through a research collaboration with Kotobuki Pharmaceutical Co., Ltd., and Astellas has exclusive global development, commercialization and manufacturing rights to gilteritinib.[2]

Gilteritinib was evaluated in ADMIRAL (NCT02421939), a Phase 3, open-label, multicenter, randomized clinical trial comparing gilteritinib with prespecified salvage chemotherapy in adult patients with relapsed or refractory *FLT3*-mutated AML.[3]

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.[4,5] 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.[6-9]

About Astellas
Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.com.

About HOVON Foundation
The HOVON-AMLSG consortium brought the HOVON 156 / AMLSG 28-18 trial to fruition under HOVON sponsorship through the collaboration with the collaborative leukaemia working groups from: Australia (ALLG), Austria & Germany (AMLSG), Belgium & Netherlands (HOVON), Finland–Norway–Sweden (Nordic AML), France (ALFA & FILO), Ireland (Cancer Trials Ireland), Lithuania, Spain (CETLAM), and Switzerland (SAKK). This broad international academic partnership exemplifies the strength of unified scientific effort in advancing AML research.

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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