Press Release

Astellas Announces Acceptance of XOSPATA® (gilteritinib) for Regulatory Review in China by the National Medical Products Administration

TOKYO, April 10, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced today a new drug application (NDA) for the oral once-daily therapy XOSPATA® (gilteritinib), for the treatment of adult patients who have relapsed (disease that has returned) or refractory (resistant to treatment) acute myeloid leukemia (AML) with a FLT3 mutation (FLT3mut+), has been accepted by the National Medical Products Administration (NMPA) for regulatory review in China.

AML is a cancer that impacts the blood and bone marrow,[1] and its incidence increases with age.[2] It is estimated that every year, around 80,000 people in China are diagnosed with leukemia.[3] AML is one of the most common types of leukemia in adults.[4]

AML patients with a FLT3 mutation have a particularly poor prognosis, with a median survival of less than six months following treatment with salvage chemotherapy.[5] The status of FLT3 mutation can change over the course of AML treatment, even after relapse. As such, a patient's mutation status should be determined to help inform the best treatment approach.[6]

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 was approved in the U.S. and Japan in 2018, Europe and Canada in 2019, and Korea, Brazil and Australia thus far in 2020 for the treatment of adult patients who have relapsed or refractory FLT3mut+ AML.[7,8,9,10,11,12,13] As of April 2020, gilteritinib is available in the U.S., Japan and selected countries in Europe.

Gilteritinib is a FMS-like tyrosine kinase 3 (FLT3) and has demonstrated inhibitory activity against FLT3-ITD, a type of FLT3mut+ that is seen in approximately one-third of patients with AML, as well as FLT3-TKD mutation. FLT3-ITD is a common driver mutation that presents with a high burden and poor prognosis.[14]

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/en.

Astellas 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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