Press Release

Astellas Submits New Drug Applications for Approval of Gilteritinib for the Treatment of FLT3mut+ Relapsed or Refractory Acute Myeloid Leukemia

TOKYO, April 24, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that it submitted on March 23, 2018, a new drug application (NDA) for marketing approval of gilteritinib (generic name) in Japan for the treatment of adult patients with FLT3 mutation-positive (FLT3mut+) relapsed or refractory acute myeloid leukemia (AML). Astellas also submitted a NDA for approval of gilteritinib in the same patient population to the U.S. Food and Drug Administration (FDA) on March 29, 2018 (U.S. time) following the submission in Japan. The applications for marketing approval for gilteritinib are based on data from the ongoing pivotal Phase 3 ADMIRAL study investigating gilteritinib in adult patients with FLT3mut+ relapsed or refractory AML.

AML is a cancer that impacts the blood and bone marrow, and its incidence increases with age. In Japan, approximately 5,500 patients are diagnosed with AML each year[1]. Gilteritinib is an investigational compound that has demonstrated inhibitory activity against both internal tandem duplication (ITD) and tyrosine kinase domain (TKD), FLT3 mutations that are seen in approximately one-third of patients with AML.

In October 2015, the Japanese Ministry of Health, Labor and Welfare (MHLW) announced the selection of gilteritinib as one of the first products designated for SAKIGAKE[2].

(1) KantarHealth. TREATMENT ARCHITECTURE: JAPAN LEUKEMIA, ACUTE MYELOID. CancerMPact® Japan, February 2017.

(2) SAKIGAKE: SAKIGAKE designation system can shorten the review period with the following 3 approaches: 1) Prioritized Consultation, 2) Substantial Pre-application Consultation and 3) Prioritized Review.
And also, the system will help promote the development with the following 2 approaches: 4) Review Partner System (to be conducted by the Pharmaceuticals and Medical Devices Agency) and 5) Substantial Post-Marketing Safety Measures.

About Gilteritinib

Astellas is currently investigating gilteritinib in various FLT3 mutation-positive AML patient populations through several Phase 3 trials. Visit http://www.clinicaltrials.gov 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. Gilteritinib has been granted Orphan Drug and Fast Track designation by the U.S. FDA, Orphan Drug Designation by the European Commission, and SAKIGAKE Designation and Orphan Drug Designation by the Japan Ministry of Health, Labor and Welfare.

About the ADMIRAL Study

The Phase 3 ADMIRAL trial is an open-label, multicenter, randomized study of gilteritinib versus salvage chemotherapy in adult patients with FLT3 mutations who are refractory to or have relapsed after first-line AML therapy. The co-primary endpoints of the trial are OS (Overall Survival) and CR (complete remission) / CRh (CR with partial hematological recovery) rate and the study is still ongoing. The study enrolled 371 patients with FLT3 mutations present in bone marrow or whole blood, as determined by central lab. Subjects have been randomized in a 2:1 ratio to receive gilteritinib (120 mg) or salvage chemotherapy.

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. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is 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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