Press Release

Astellas Announces Approval in Japan for XOSPATA® 40 mg Tablets for the Treatment of FLT3mut+ Relapsed or Refractory AML

TOKYO, September 21, 2018 -Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that XOSPATA® Tablets 40 mg (generic name: gilteritinib), a FLT3 (FMS-like tyrosine kinase 3) inhibitor received manufacturing and marketing approval for the treatment of FLT3 mutation-positive relapsed or refractory acute myeloid leukemia (AML) in Japan.

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]. XOSPATA® 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.

This approval is based on the CR/CRh[2] rate results from the interim analysis of the multinational Phase 3 ADMIRAL study. In October 2015, gilteritinib was designated as one of the first products in Japan to be included in the SAKIGAKE[3] designation system. A similar application for approval was filed in the United States in March, 2018 and is currently under review.

With this approval, Astellas hopes to further contribute to the health of patients suffering from AML and to support healthcare professionals involved in the treatment of AML by providing new treatment options.

Astellas reflected the impact from this approval in its financial forecasts of the current fiscal year ending March 31, 2019.

Product overview

Trade name	XOSPATA® 40mg Tablets
Generic name	gilteritinib
Indication	Relapsed or refractory acute myeloid leukemia with *FLT3* mutations
Dosage and administration	The usual recommended starting dose of gilteritinib for an adult is 120 mg once daily orally.The dosage may be adjusted depending on the patient's condition. The daily maximum dose of XOSPATA should be 200 mg
Date of approval	September 21, 2018

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 Designation 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 / CRh[2] 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.

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

(2) CR: complete remission, CRh: CR with partial hematological recovery

(3) SAKIGAKE: The 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 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

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.

###

Contacts for inquiries or additional information:
Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473