Press Release

Launch of XOSPATA® Tablets 40 mg in Japan

- Provides a new therapeutic option for patients with AML -

TOKYO, December 3, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced the launch of the FLT3 (FMS-like tyrosine kinase 3) inhibitor XOSPATA® Tablet 40 mg (generic name: gilteritinib fumarate, "XOSPATA®") in Japan for the indication of relapsed or refractory acute myeloid leukemia (AML) with FLT3 mutations.

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].It has also been seen that approximately 30 percent of patients with AML have mutations in a protein called FLT3, a receptor tyrosine kinase that is involved in the growth of cancer cells.

XOSPATA® is believed to suppress the growth of mutant tumor cells (ITD) by inhibiting mutations in two types of FLT3 mutations: internal tandem duplication and tyrosine kinase domain (TKD).

In October 2015, gilteritinib fumarate was granted SAKIGAKE[2] designation for first relapsed or refractory AML with FLT3 mutations in Japan. In September 2018, it was approved for the indication of relapsed or refractory AML with FLT3 mutations based on the results of CR/CRh rate[3] in the interim analysis of the multinational phase 3 ADMIRAL trial. It was also been approved for a similar indication in the United States on November 28, 2018 local time.

When administering XOSPATA®, a companion diagnostic (CDx) should be used to confirm that the patient is positive for the FLT3 mutation. This approach supports the promotion of precision medicine, which may provide optimal treatment for individual patients.

By providing XOSPATA® as a new treatment option, Astellas is contributing to the health of patients with AML and supporting healthcare professionals involved in the treatment of AML.

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

Product overview

Trade name	XOSPATA® 40 mg 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
Date of NHI drug price listing	November 20, 2018
Date of Launch	December 3, 2018

Product photo

About gilteritinib

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. 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.

About the ADMIRAL trial

The Phase 3 ADMIRAL trial (NCT02421939) was 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 primary endpoints of the trial are Overall Survival (OS) and complete remission/complete remission with partial hematologic recovery (CR/CRh) [3] rates. The study enrolled 371 patients with FLT3 mutations present in bone marrow or whole blood, as determined by central lab. Subjects were randomized in a 2:1 ratio to receive gilteritinib (120 mg[4]) or salvage chemotherapy.

(1) Annual Incidence in 2017 in U.S., EU5 and JP. CancerMPact (Synix Inc./Kantar Health)

(2) 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

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

(4) Gorcea CM, Burthem J, Tholouli E. ASP2215 in the treatment of relapsed/refractory acute myeloid leukemia with FLT3 mutation: background and design of the ADMIRAL trial. Future Oncol (Epub) 03-02-2018.

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.

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