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USFDA grants Priority Review to Astellas's NDA for Gilteritinib

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Gilteritinib is being developed for the treatment of adult patients who have relapsed or refractory Acute Myeloid Leukemia

Japan's Astellas Pharma recently announced that the U.S. Food and Drug Administration (FDA) has accepted, with Priority Review, the company's New Drug Application (NDA) for gilteritinib for the treatment of adult patients who have relapsed or refractory Acute Myeloid Leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. Currently, there are no FLT3-targeting agents approved for the treatment of relapsed or refractory FLT3 mutation-positive (FLT3mut+) AML.

Gilteritinib was discovered through a research collaboration with Kotobuki Pharmaceutical , and Astellas has exclusive global rights to develop, manufacture and potentially commercialize gilteritinib.

"FLT3 mutations impact approximately 30 percent of AML patients and are often associated with poor survival outcomes. Many with this condition relapse after treatment or don't respond to currently available treatments. Simply put, they need more options," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "The FDA's acceptance of this NDA, with Priority Review, represents a significant milestone for gilteritinib and Astellas in our mission to help AML patients and the physicians who treat them."

The NDA is based on the ongoing Phase 3 ADMIRAL trial investigating gilteritinib for the treatment of adult patients with FLT3mut+ relapsed or refractory AML. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is November 29, 2018.

The FDA grants Priority Review designation to applications for drugs that, if approved, may offer significant improvements in the safety and effectiveness of the treatment of serious conditions when compared to standard applications. Under Priority Review, the FDA aims to take action on an application within six months of NDA filing, as compared to ten months under standard review.

Previously, gilteritinib was granted both Orphan Drug designation and Fast Track designation by the U.S. FDA. Gilteritinib also received Orphan Designation from the European Commission (EC) and Orphan Drug Designation from the Japan

Ministry of Health, Labor and Welfare (MHLW). The MHLW also granted SAKIGAKE designation to gilteritinib for relapsed/refractory AML.

Acute Myeloid Leukemia (AML) is a cancer that impacts the blood and bone marrow, and its incidence increases with age. The American Cancer Society estimates that in 2018, approximately 19,000 new patients will be diagnosed with AML in the U.S. In Western Europe, there are around 13,000 new cases of AML every year. In Japan, approximately 5,500 patients are diagnosed with AML each year.