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Astellas launches XOSPATA (gilteritinib) in Singapore to treat adult Leukaemia patients

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An oral monotherapy for Relapsed/Refractory Acute Myeloid Leukaemia (AML) with a FLT3 Mutation

Astellas Pharma Inc. announced on March 31, 2021, that XOSPATA® (generic name: gilteritinib) is now available for prescription in Singapore for the treatment of adult patients who have relapsed or refractory (resistant to treatment) Acute Myeloid Leukaemia (AML) with a *FLT3* mutation. An oral monotherapy, XOSPATA is the first and only FLT3-targeting agent approved by the HSA for the treatment of relapsed or refractory *FLT3* mutation-positive (*FLT3*mut+) AML.

Gilteritinib is one of the few advances for the treatment of AML over the past 40 years, and has the potential to improve treatment outcomes for AML with two forms of the common *FLT3* gene mutation – *FLT3* internal tandem duplication (ITD) and *FLT3* tyrosine kinase domain (TKD). Patients' *FLT3*mut+ status can change over the course of AML treatment, particularly following relapse. Due to the poor outcomes associated with the *FLT3*-ITD mutation, the most common driver mutation associated with a higher leukaemic burden, confirming patients' *FLT3* mutation status following relapse is important to help inform the best treatment approach.

"AML is one of the most difficult cancers to treat, and patients with a *FLT3* mutation have a particularly poor prognosis. In patients who relapse or are refractory to first-line chemotherapy, only a minority will respond to second-line (salvage) chemotherapy. The median survival of non-responders is less than six months," said Dr. Yvonne Loh, Raffles Hospital. "Gilteritinib provides a clinically meaningful treatment option for patients that have relapsed or refractory AML with a *FLT3* mutation, backed by substantial safety and efficacy data."

XOSPATA was approved by the Singapore Health Sciences Authority (HSA) on January 28, 2021. The approval was based on results from the Phase 3 ADMIRAL trial, which investigated gilteritinib versus salvage chemotherapy in adult patients with relapsed or refractory *FLT3*mut+ AML.