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General AML, FLT3

FDA grants Orphan Drug Designation to MAX-40279 for the treatment of AML

Cynthia Umukoro | Apr 03, 2018

On 29 March 2018, the US Food and Drug Administration (FDA) granted Orphan Drug Designation to MAX-40279, a multi-kinase targeted inhibitor, for the treatment of patients with Acute Myeloid Leukemia (AML).

Mutations in the fms like tyrosine kinase (*FLT3*) gene represent one of the most commonly encountered, and clinically challenging, classes of AML mutations and it is expressed in approximately 30% of patients. MAX-40279 is a dual inhibitor of FLT3 and fibroblast growth factor receptor (FGFR). According to the drug manufacturers, MaxiNovel Pharmaceuticals, MAX-40279 "demonstrated potent inhibition of both FLT3 and FGFR with excellent drug concentration in the bone marrow" in preclinical studies. Additionally, MAX-40279 was designed to overcome the drug resistance experienced by current FLT3 inhibitors due to bone marrow FGF/FGFR pathway activation.

At present, MAX-40279 is being investigated in a phase I dose escalation study (NCT03412292), which is evaluating the safety and tolerability of MAX-40279 in patients with AML. The primary endpoints of the study include incidence of adverse events and determination of the maximum tolerated dose.

References

1. BusinessWire: MaxiNovel Pharmaceuticals, Inc. Announces FDA Orphan Drug Designation for MAX-40279 for the Treatment of Acute Myeloid Leukemia (AML). 2018 Mar 29.https://www.businesswire.com/news/home/20180329005826/en/MaxiNovel-Pharmaceuticals-Announces-FDA-Orphan-Drug-Designation.[Accessed 2018 Apr 03].

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