AMLGlobalPortal

FLT3

Orphan Drug Designation granted for quizartinib in Japan for the treatment of FLT3-mutated acute myeloid leukemia

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On 11 September 2018, Japan's Ministry of Health, Labor, and Welfare (MHLW) granted Orphan Drug Designation to quizartinib, an oral, highly potent and selective FMS-like tyrosine kinase 3 (FLT3) inhibitor, for the treatment of adult patients with *FLT3*-mutated acute myeloid leukemia (AML). This comes after Breakthrough Therapy Designation was granted to quizartinib by the U.S. Food and Drug Administration (FDA) last month.

The pivotal phase III randomized QuANTUM-R study is assessing the efficacy and safety of quizartinib (60-mg, with a 30-mg lead-in for 15 days) *versus* salvage chemotherapy (SC) in patients with R/R *FLT3-ITD*-mutated AML. Data from this study showed that quizartinib significantly prolonged overall survival in patients with R/R *FLT3-ITD* AML compared to SC. More results from this phase III randomized study are reported here.

Jorge Cortes, in an interview with the AML Global Portal (AGP), highlighted that the QuANTUM-R trial was a "very positive study", and he hopes that it leads to a "regulatory approval" for quizartinib as it "offers an advantage" over the current treatment options for these difficult to treat patients.

References

1. PR Newswire: Daiichi Sankyo's FLT3 Inhibitor Quizartinib Receives Orphan Drug Designation from Japanese MHLW for FLT3-Mutated AML. 2018 Sep 11. https://www.prnewswire.com/news-releases/daiichi-sankyos-flt3-inhibitor-quizartinib-receives-orphan-drug-designation-from-japanese-mhlw-for-flt3-mutated-aml-300709801.html [Accessed 2018 Sep 12].