AMLGlobalPortal

IDH1/2

FDA grants ivosidenib (Tibsovo®) priority review for the treatment of patients with newly diagnosed *IDH1*-mutant acute myeloid leukemia

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On 20 February 2019, the US Food and Drug Administration (FDA) accepted a supplemental new drug application (sNDA) and granted priority review to ivosidenib, a first-in-class, oral, selective inhibitor of mutations in isocitrate dehydrogenase-1 (*IDH1*), for the treatment of patients with newly diagnosed *IDH1*-mutant acute myeloid leukemia (AML). This comes after ivosidenib received FDA approval for the treatment of patients with *IDH1*-mutant relapsed/refractory AML.

The sNDA for ivosidenib was based on the first-in-human phase I dose-escalation and expansion study (NCT02074839), which assessed the safety and efficacy of single-agent ivosidenib in patients with previously untreated AML. The results from this trial showed that single-agent ivosidenib therapy induced an overall response rate of 57.6% (95% CI, 39.2–74.5) among newly diagnosed patients with *IDH1*-mutant AML. Furthermore, ivosidenib was shown to induce *IDH1* mutational clearance in bone marrow mononuclear cells in 64% of patients who achieved complete remission (CR) or CR with partial hematologic recovery (CRh). Data from this trial was presented at the 60th Annual Society of Hematology Annual Meeting and Exposition, read more here.

According to the drug manufacturers, ivosidenib treatment regimens could “benefit from this targeted therapy”, as at present patients with newly diagnosed *IDH1*-mutant AML “are currently offered only palliative care.”

References

1. TargetedOnc. Ivosidenib receives priority review from FDA for frontline IDH1+ AML. https://www.targetedonc.com/news/ivosidenib-receives-priority-review-from-fda-for-frontline-idh1-aml [Accessed 2019 Feb 21]