FDA Approves Inrebic (Fedratinib) for Myelofibrosis

This is the second drug the FDA has approved for myelofibrosis; the first came in 2011.

August 16, 2019 By Food and Drug Administration (FDA)

On August 16, 2019, the Food and Drug Administration approved fedratinib (INREBIC, Impact Biomedicines, Inc.) for adults with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

Efficacy was investigated in JAKARTA (NCT01437787), a double-blind, randomized, placebo-controlled trial in 289 patients with intermediate-2 or high-risk MF, post-polycythemia vera MF, or post-essential thrombocythemia MF with splenomegaly. Patients were randomized to receive either INREBIC 500 mg (N=97), 400 mg (n=96) or placebo (n=96) once daily for at least 6 cycles.

The primary efficacy outcome was the proportion of patients achieving ≥35% reduction from baseline in spleen volume at the end of cycle 6 measured by MRI or CT with a follow-up scan 4 weeks later. Of the 96 patients treated with the recommended dose (400 mg) of fedratinib, 35 (37%) achieved a ≥ 35% reduction in spleen volume, compared with 1 of 96 patients who received placebo ($p<0.0001$). The median duration of spleen response was 18.2 months for the fedratinib 400 mg group. In addition, 40% of patients who received 400 mg experienced a ≥ 50% reduction in myelofibrosis-related symptoms, whereas only 9% of patients receiving placebo experienced a decline in these symptoms.

The prescribing information for fedratinib includes a Boxed Warning to advise health care professionals and patients about the risk of serious and fatal encephalopathy, including Wernicke's encephalopathy. Health care professionals are advised to assess thiamine levels in all patients prior to starting fedratinib, periodically during treatment, and as clinically indicated. If encephalopathy is suspected, fedratinib should be immediately discontinued and parenteral thiamine initiated.

The most common adverse reactions (≥ 20%) in patients who received fedratinib were diarrhea, nausea, anemia, and vomiting.

The recommended fedratinib dose is 400 mg orally once daily with or without food for patients with a baseline platelet count of greater than or equal to 50 x 109/L. Reduce dose for patients taking strong CYP3A inhibitors or for patients with severe renal impairment.

View full prescribing information for INREBIC.

Fedratinib was granted priority review and orphan drug designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

Check out recent approvals at the OCE's podcast, Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.).

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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