Jakafi® (ruxolitinib) – New indication

- On September 22, 2021, Incyte announced the FDA approval of Jakafi (ruxolitinib), for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

- Jakafi is also approved for myelofibrosis, polycythemia vera, and acute graft-versus-host disease.

- The approval of Jakafi for the new indication was based on REACH-3, a randomized, open-label study in 329 patients with corticosteroid-refractory cGVHD after allogeneic stem cell transplantation. Patients were randomized to receive either Jakafi or best available therapy (BAT). The efficacy of Jakafi was based on overall response rate (ORR) through Cycle 7 Day 1.

    — The ORR was 70% with Jakafi vs. 57% with BAT (treatment difference: 13%; 95% CI: 3, 23).
    — The median duration of response, calculated from first response to progression, death, or new systemic therapies for cGVHD, was 4.2 months (95% CI: 3.2, 6.7) for Jakafi vs. 2.1 months (95% CI: 1.6, 3.2) with BAT.

- The most common hematologic adverse reactions (> 35%) with Jakafi use in cGVHD were anemia and thrombocytopenia. The most common nonhematologic adverse reactions (≥ 20%) were infections (pathogen not specified) and viral infections.

- The recommended starting dose of Jakafi for cGVHD is 10 mg given orally twice daily. Tapering the dose can be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. Taper Jakafi by one dose level approximately every 8 weeks (10 mg twice daily to 5 mg twice daily to 5 mg once daily). If GVHD signs or symptoms recur during or after the taper of Jakafi, retreatment should be considered.

    — Refer to the Jakafi drug label for dosing for all its other indications.

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