Leqselvi™ (deuruxolitinib) – New drug approval

- On July 25, 2024, Sun Pharma announced the FDA approval of Leqselvi (deuruxolitinib), for the treatment of adults with severe alopecia areata.
    - Leqselvi is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
- Alopecia areata is an autoimmune disease in which the immune system attacks hair follicles, resulting in partial or complete loss of hair on the scalp and body.
    - Alopecia areata affects around 700,000 people in the U.S., and 300,000 have severe alopecia areata.
- Leqselvi is an oral selective inhibitor of JAK1 and JAK2. JAKs mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function.
- The efficacy of Leqselvi was established in two randomized, double-blind, placebo-controlled studies (AA-1 and AA-2) in 1,209 patients with alopecia areata. Patients were randomized to Leqselvi 8 mg twice daily, deuruxolitinib 12 mg twice daily, or placebo twice daily. Deuruxolitinib 12 mg is not FDA-approved. The primary endpoint for both trials assessed the proportion of subjects who achieved at least 80% scalp hair coverage (Severity of Alopecia Tool [SALT] score of ≤ 20) at week 24.
    - In study AA-1, at week 24, 29% of Leqselvi 8 mg twice daily patients vs. 1% of placebo patients had a SALT score ≤ 20 (common risk difference, 28%; 95% CI: 23, 33).
    - In study AA-2, at week 24, 32% of Leqselvi 8 mg twice daily patients vs. 1% of placebo patients had a SALT score ≤ 20 (common risk difference, 31%; 95% CI: 25, 37).
- Leqselvi carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events and thrombosis.
- Leqselvi is contraindicated in patients who are CYP2C9 poor metabolizers or who are using moderate or strong CYP2C9 inhibitors.
- Additional warnings and precautions for Leqselvi include gastrointestinal perforations; lipid elevations, anemia, neutropenia, and lymphopenia; and immunizations.
- The most common adverse reactions (≥ 1%) with Leqselvi use were headache, acne, nasopharyngitis, increased blood creatine phosphokinase, hyperlipidemia, fatigue, increased weight, lymphopenia, thrombocytosis, anemia, skin and soft tissue infections, neutropenia, and herpes.
- The recommended dose of Leqselvi is 8 mg orally twice daily, with or without food.
- Sun Pharma's launch plans for Leqselvi are pending. Leqselvi will be available as an 8 mg tablet.

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