Olumiant® (baricitinib) – New indication

- On June 13, 2022, the FDA announced the approval of Eli Lilly's Olumiant (baricitinib), for the treatment of adult patients with severe alopecia areata.
    - Olumiant is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
- Olumiant is also approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers and for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
- Alopecia areata is an autoimmune disorder that often appears as patchy baldness. In alopecia areata, the body attacks its own hair follicles, causing hair to fall out, often in clumps. Severe alopecia areata affects more than 300,000 people in the U.S. each year.
- Olumiant is a JAK inhibitor which blocks the activity of one or more of a specific family of enzymes, interfering with the pathway that leads to inflammation. It is the first FDA approved treatment for alopecia areata.
- The approval of Olumiant for the new indication was based on two randomized, double-blind, placebo-controlled studies (Studies AA-1 and AA-2) in a total of 1,200 patients, with alopecia areata, who had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months. Patients received Olumiant 2 mg, Olumiant 4 mg, or placebo. Both studies assessed the proportion of patients who achieved at least 80% scalp hair coverage (SALT score of ≤ 20) at week 36 as the primary endpoint.
    - In AA-1, the primary endpoint was met in 5%, 22%, and 35% of patients with placebo, Olumiant 2 mg, and Olumiant 4 mg, respectively. For Olumiant 2 mg, the difference vs. placebo was 16% (95% CI: 10, 23) and for Olumiant 4 mg, the difference vs. placebo was 30% (95% CI: 23, 36).
    - In AA-2, the primary endpoint was met in 3%, 17%, and 32% of patients with placebo, Olumiant 2 mg, and Olumiant 4 mg, respectively. For Olumiant 2 mg, the difference vs. placebo was 15% (95% CI: 8, 22) and for Olumiant 4 mg, the difference vs. placebo was 30% (95% CI: 23, 36).
- Olumiant carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The most common adverse reactions (≥ 1%) with Olumiant use were upper respiratory tract infections, headache, acne, hyperlipidemia, increased creatine phosphokinase, urinary tract infection, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and increased weight.
- The recommended dose of Olumiant for the treatment of alopecia areata is 2 mg once daily orally, with or without food. The dose should be increased to 4 mg once daily if the response to treatment is not adequate.

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- For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, treating with 4 mg once daily should be considered.
- Once patients achieve an adequate response to treatment with 4 mg, the dosage should be decreased to 2 mg once daily.
- Refer to the Olumiant drug label for dosing for its other indications.

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