Zoryve® (roflumilast) – New indication, new strength

- On July 9, 2024, Arcutis Biotherapeutics announced the FDA approval of Zoryve (roflumilast), for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
- In addition to the new indication, the FDA approved a new 0.15% strength of Zoryve.
- Zoryve 0.3% is also approved for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.
- The approval of Zoryve for the new indication was based on two randomized, double-blind, vehicle-controlled studies (INTEGUMENT-1 and INTEGUMENT-2) in a total of 1,337 adult and pediatric patients 6 years of age and older with mild to moderate atopic dermatitis. Patients were randomized to receive Zoryve or vehicle cream for 4 weeks. The primary endpoint was the proportion of patients who achieved validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) treatment success at week 4. Success was defined as a score of "Clear" (0) or "Almost Clear" (1), plus a 2-grade improvement from baseline.
    - In INTEGUMENT-1, vIGA-AD success was achieved in 32.0% of patients with Zoryve vs. 15.2% with vehicle cream (treatment difference 17.4, 95% CI: 11.09, 23.75).
    - In INTEGUMENT-2, vIGA-AD success was achieved in 28.9% of patients with Zoryve vs. 12.0% with vehicle cream (treatment difference 16.5, 95% CI: 10.61, 22.42).
- The most common adverse reactions (≥ 1%) with Zoryve use for atopic dermatitis were headache, nausea, application site pain, diarrhea, and vomiting.
- Zoryve is applied to affected areas once daily.
- Arcutis Biotherapeutics plans to launch Zoryve 0.15% cream by the end of July 2024.

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