Zoryve® (roflumilast) – New formulation approval

- On December 15, 2023, Arcutis Biotherapeutics announced the FDA approval of Zoryve (roflumilast), for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.
- Another formulation of Zoryve, roflumilast cream 0.3%, is approved by the FDA for the topical treatment of plaque psoriasis in individuals 6 years of age and older.
- The efficacy of Zoryve was established in two randomized, double-blind, vehicle-controlled studies (STRATUM and Trial 203) in a total of 683 adult and pediatric patients with seborrheic dermatitis involving the scalp, face, and/or body. In each study, patients were randomized to receive Zoryve foam, 0.3%, or vehicle foam applied once daily for 8 weeks. The primary endpoint was the proportion of patients who achieved Investigator Global Assessment (IGA) treatment success at week 8. Success was defined as a score of "Clear" (0) or "Almost Clear" (1), plus a 2-grade improvement from baseline.
    - In STRATUM, 79.5% and 58.0% of patients achieved IGA success with Zoryve and vehicle foam, respectively (difference 20.6, 95% CI: 11.2, 30.0).
    - In Trial 203, 73.1% and 40.8% of patients achieved IGA success with Zoryve and vehicle foam, respectively (difference 33.8, 95% CI: 20.3, 47.4).
- Zoryve is contraindicated in patients with moderate to severe liver impairment.
- A warning and precaution for Zoryve is flammability.
- The most common adverse reactions (≥ 1%) with Zoryve use were nasopharyngitis, nausea, and headache.
- Zoryve should be applied as a thin layer once daily to affected areas on skin and/or scalp when they are not wet.
- Arcutis Biotherapeutics plans to launch Zoryve by the end of January 2024. Zoryve will be available as a 0.3% foam (3 mg of roflumilast per gram in 60-gram pressurized cans).