

## Zoryve<sup>®</sup> (roflumilast) – Expanded indication

- On October 6, 2023, [Arcutis Biotherapeutics announced](#) the FDA approval of [Zoryve \(roflumilast\)](#), for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
  - Zoryve was previously approved for the same indication in patients 12 years of age and older.
- The approval of Zoryve for the expanded indication was supported by data from two 8-week, vehicle-controlled safety and efficacy trials which included 18 pediatric subjects 6 to 17 years of age, of whom 11 received Zoryve. Use of Zoryve in pediatric patients 6 to less than 12 years of age is also supported by data from one 4-week, open-label, safety and pharmacokinetic study which included 20 pediatric subjects 6 to less than 12 years of age.
- Zoryve should be applied to the affected areas once daily and rubbed in completely.