Vtama® (tapinarof) – New indication

- On December 12, 2024, the FDA approved Dermavant Sciences' Vtama (tapinarof), for the topical treatment of **atopic dermatitis in adults and pediatric patients 2 years of age and older**.
- Vtama is also approved for the topical treatment of plaque psoriasis in adults.
- The approval of Vtama for the new indication was based on two randomized, double-blind, vehicle-controlled studies in 813 adult and pediatric patients 2 years of age and older with atopic dermatitis (ADORING 1 and ADORING 2). Patients were randomized to Vtama or vehicle cream for 8 weeks. The primary efficacy endpoint in both studies was the proportion of subjects who achieved treatment success, defined as a vIGA-AD score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline.
    - In ADORING 1, **vIGA-AD was achieved in 45% and 14% of patients with Vtama and vehicle cream**, respectively (treatment success difference 32, 95% CI: 23, 40).
    - In ADORING 2, **vIGA-AD was achieved in 46% and 18% of patients with Vtama and vehicle cream**, respectively (treatment success difference 29, 95% CI: 19, 38).
- The most common adverse reactions (≥ 1%) with Vtama use for atopic dermatitis were upper respiratory tract infection, **folliculitis**, lower respiratory tract infection, headache, asthma, vomiting, ear infection, pain in extremity, and abdominal pain.
- Vtama is administered as a thin layer **applied topically to affected areas once daily.**