Vtama® (tapinarof) – New drug approval

- On May 24, 2022, Dermavant Sciences announced the FDA approval of Vtama (tapinarof), for the topical treatment of plaque psoriasis in adults.

- Plaque psoriasis, also called psoriasis vulgaris, affects about 80 to 90% of people with psoriasis (psoriasis affects about 8 million Americans). In people with light skin, plaque psoriasis is characterized by raised, red or pink patches of skin with silvery-white scale. People with black or brown skin are more likely to have brown or violet-colored patches with silvery-white or gray scale. The scale can be itchy, painful, and disfiguring.

- Vtama is a first-in-class, steroid-free, aryl hydrocarbon receptor agonist. The specific mechanisms by which Vtama exerts its therapeutic action in psoriasis patients are unknown.

- The efficacy of Vtama was established in two randomized, double-blind, vehicle-controlled studies (PSOARING 1 and PSOARING 2) in 1,025 adults with plaque psoriasis. Patients received Vtama cream or vehicle cream applied once daily for 12 weeks to any lesion regardless of anatomic location. The primary endpoint in both studies was the proportion of patients who achieved treatment success, defined as a Physician's Global Assessment (PGA) score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline.

    — In PSOARING 1, PGA treatment success was achieved in 36% and 6% of patients treated with Vtama vs. placebo, respectively (treatment difference 29, 95% CI: 22, 36).
    — In PSOARING 2, PGA treatment success was achieved in 40% and 6% of patients treated with Vtama vs. placebo, respectively (treatment difference 34, 95% CI: 27, 41).

- The most common adverse reactions (≥ 1%) with Vtama use were folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza.

- Vtama should be applied as a thin layer to affected areas once daily.

- Dermavant Sciences plans to launch Vtama in June 2022. Vtama will be available as a 1% cream (60-gram tube).