Duobrii™ (halobetasol propionate and tazarotene) – New drug approval

- On April 25, 2019, Bausch Health announced the FDA approval of Duobrii (halobetasol propionate and tazarotene) lotion, for the topical treatment of plaque psoriasis in adults.

- Approximately 7.5 million people live with psoriasis in the U.S. Plaque psoriasis is the most common type of psoriasis, a chronic, non-contagious skin disease that alters the life cycle of skin cells, causing them to build up rapidly on the surface of the skin.

- Duobrii is a combination product with a corticosteroid (halobetasol) and retinoid (tazarotene).

- The efficacy of Duobrii was evaluated in two double-blind studies in 418 patients with moderate-to-severe plaque psoriasis. Patients were randomized to Duobrii or vehicle. The primary efficacy endpoint was the proportion of subjects with "treatment success" at week 8. Treatment success was defined as at least a 2-grade improvement from baseline in the Investigator's Global Assessment (IGA) score and an IGA score equating to "clear" or "almost clear".

    — In study 1, treatment success was achieved in 36% and 7% of patients receiving Duobrii and placebo, respectively.
    — In study 2, treatment success was achieved in 45% and 13% of patients receiving Duobrii and placebo, respectively.

- Duobrii is contraindicated in pregnancy.

- Warnings and precautions of Duobrii include embryofetal risk, hypothalamic-pituitary-adrenal (HPA) axis suppression and other unwanted systemic glucocorticoid effects, local adverse reactions, photosensitivity and risk for sunburn, ophthalmic adverse reactions, and concomitant skin infections.

- The most common adverse reactions with Duobrii use were contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%).

- The recommended dose of Duobrii is a thin layer application once daily to cover only affected areas.

    — The total dosage should not exceed approximately 50 g per week because of the potential for the drug to suppress the HPA axis.
    — Treatment should be discontinued when control is achieved.
    — If a bath or shower is taken prior to application, the skin should be dry before applying the lotion.
    — Application should be avoided on the face, groin, or in the axillae.

- Bausch Health plans to launch Duobrii in June 2019. Duobrii will be available as a 0.01% (halobetasol)/0.045% (tazarotene) lotion.