Arazlo™ (tazarotene) – New drug approval

- On December 19, 2019, Bausch Health announced the FDA approval of Arazlo (tazarotene) lotion**,** for the topical treatment of acne vulgaris in patients 9 years of age and older.

- Arazlo is the first tazarotene acne treatment available in a lotion formation. Tazarotene is currently available generically as a topical cream and brand topical foam (Fabior®), topical gel (Tazorac®), and another brand cream (Avage®). Tazarotene is also available as a lotion in combination with halobetasol (Duobrii™).

    — The generic topical cream and gel are approved for plaque psoriasis and acne vulgaris. The topical foam is approved for acne vulgaris.
    — Avage is approved as an adjunctive agent for use in the mitigation (palliation) of facial fine wrinkling, facial mottled hyper- and hypopigmentation, and benign facial lentigines in patients who use comprehensive skin care and sunlight avoidance programs.
    — Duobrii is approved for the treatment of plaque psoriasis.

- The efficacy of Arazlo was established in two randomized, double-blind studies in 1,614 patients with facial acne vulgaris. Patients received Arazlo or vehicle. The efficacy endpoints of success on the Evaluator's Global Severity Score (EGSS), absolute change in non-inflammatory lesion count, and absolute change in inflammatory lesion count were assessed at week 12. Success on the EGSS was defined as at least a 2-grade improvement from baseline and an EGSS score of clear (0) or almost clear (1).

    — In study 1, success on the EGSS was achieved in 25.5% and 13% of patients receiving Arazlo and vehicle, respectively (difference 12.5, 95% CI: 7.1, 17.9). The mean absolute reduction in non-inflammatory facial lesions was 21.0 and 16.4, respectively (difference 4.5, 95% CI: 2.6, 6.4) and the mean absolute reduction in inflammatory facial lesions was 15.6 and 12.4 (difference 3.3, 95% CI: 1.9, 4.7).
    — In study 2, success on the EGSS was achieved in 29.6% and 17.3% of patients receiving Arazlo and vehicle, respectively (difference 12.3, 95% CI: 6.5, 18.1). The mean absolute reduction in non-inflammatory facial lesions was 24.6 and 16.6, respectively (difference 8.1, 95% CI: 5.9, 10.2) and the mean absolute reduction in inflammatory facial lesions was 16.7 and 13.4 (difference 3.2, 95% CI: 1.9, 4.5).

- Arazlo is contraindicated in pregnancy.

- Warnings and precautions for Arazlo include embryofetal toxicity, skin irritation, and photosensitivity and risk for sunburn.

- The most common adverse reactions (≥ 1% and greater than the vehicle group) with Arazlo use were application site reactions: pain, dryness, exfoliation, erythema and pruritus.

- The recommended administration of Arazlo is a thin layer to the affected areas once daily.

- Bausch Health plans to launch Arazlo in the first half of 2020. Arazlo will be available as a 0.045% lotion.