Emrosi™ (minocycline) – New drug approval

- On November 4, 2024, Journey Medical announced the FDA approval of Emrosi (minocycline), to treat inflammatory lesions (papules and pustules) of rosacea in adults.
    - This formulation of minocycline has not been evaluated in the treatment or prevention of infections.
    - To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Emrosi should only be used as indicated.

- The efficacy of Emrosi was established in two randomized, double-blind, active-and placebo-controlled studies (Trial MVOR-1 and Trial MVOR-2) in 653 adults with papulopustular rosacea. Patients were randomized to Emrosi, doxycycline, or placebo for up to 16 weeks. The co-primary efficacy endpoints were the proportion of patients with Investigator's Global Assessment (IGA) treatment success at week 16 (defined as an IGA score of 0 ["clear"] or 1 ["near clear"] with at least a 2-grade reduction from baseline) and the absolute change from baseline in total inflammatory lesion counts at week 16, in the Emrosi group compared to the placebo group.
    - In Trial MVOR-1, IGA treatment success was achieved in 65%, 46%, and 31% of patients with Emrosi, doxycycline (difference 18, 95% CI: 5, 31), and placebo (difference of 33, 95% CI: 20, 46), respectively. In Trial MVOR-2, IGA treatment success was achieved in 60%, 31%, and 27% of patients with Emrosi, doxycycline (difference 28, 95% CI: 17, 39), and placebo (difference 34, 95% CI: 21, 47).
    - In Trial MVOR-1, the mean absolute change in inflammatory lesion counts were -20.6, -15.6, and -11.4 with Emrosi, doxycycline (difference -5.1, 95% CI: -7.2, -2.9), and placebo (difference -9.3, 95% CI: -11.6, -6.9), respectively. In Trial MVOR-2, the mean absolute change in inflammatory lesion counts were -18.1, -14.6, and -11.2 with Emrosi, doxycycline (difference -3.4, 95% CI: -5.4, -1.5), and placebo (difference -6.9, 95% CI: -9.1, -4.6), respectively.

- Warnings and precautions for Emrosi include hypersensitivity reaction and serious skin reactions; tooth discoloration and enamel hypoplasia; inhibition of bone growth; *Clostridioides difficile*-associated diarrhea (antibiotic-associated colitis); hepatotoxicity; central nervous system effects; idiopathic intracranial hypertension; autoimmune syndromes; metabolic effects; photosensitivity; tissue hyperpigmentation; development of drug-resistant bacteria; superinfection; and laboratory monitoring.

- The most common adverse reaction (≥ 1%) with Emrosi use was dyspepsia.

- The recommended dose of Emrosi is one capsule (40 mg) taken orally, once daily. Higher doses have not shown to be of additional benefit in the treatment of rosacea.

- Journey Medical plans to launch Emrosi late in the first quarter or early in the second quarter of 2025. Emrosi will be available as a 40 mg extended-release capsule.