## Seysara™ (sarecycline) – New drug approval

- On October 2, 2018, Paratek Pharmaceuticals and Almirall announced the FDA approval of Seysara (sarecycline), for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.
    - Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. Seysara has not been evaluated in the treatment of infections.
    - To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara should be used only as indicated.
- Acne vulgaris is a common chronic skin disease involving blockage and/or inflammation of hair follicles and their accompanying sebaceous gland. Acne can present as non-inflammatory lesions, inflammatory lesions, or a mixture of both, affecting mostly the face but also the back and chest.
    - Acne vulgaris affects 80% of Americans at some time during their lives. Of those affected, 20% have severe acne, which can result in permanent physical and mental scarring.
- Seysara is a tetracycline-derived antibiotic. The exact mechanism of action of Seysara in treating acne is not known.
- The safety and efficacy of Seysara were assessed in two 12-week studies comparing Seysara vs. placebo. Efficacy was assessed in a total of 2,002 patients ≥ 9 years of age. The two co-primary endpoints were: (1) percentage of patients with Investigator's Global Assessment (IGA) success and (2) absolute reduction from baseline in inflammatory lesion counts.
    - In study 1, IGA success for Seysara and placebo was 21.9% and 10.5%, respectively; the mean absolute reduction from baseline in inflammatory lesions was 15.3 and 10.2, respectively.
    - In study 2, IGA success for Seysara and placebo was 22.6% and 15.3%, respectively; the mean absolute reduction from baseline in inflammatory lesions was 15.5 and 11.1, respectively.
- Warnings and precautions of Seysara include teratogenic effects, *Clostridium difficile* associated diarrhea, central nervous system effects, intracranial hypertension, photosensitivity, development of drug-resistant bacteria, and superinfection/potential for microbial overgrowth.
- The most common adverse reaction (≥ 1%) with Seysara use was nausea.
- The recommended dose of Seysara is weight-based, once daily, with or without food. If there is no improvement after 12 weeks, treatment with Seysara should be reassessed.

| Body Weight | Tablet Strength |
|---|---|
| 33 to 54 kg | 60 mg |
| 55 to 84 kg | 100 mg |
| 85 to 136 kg | 150 mg |

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- Almirall plans to launch Seysara in January 2019. Seysara will be available as 60 mg, 100 mg, and 150 mg tablets.