Minolira™ (minocycline) – New drug approval

- On May 8, 2017, the FDA approved Dr. Reddy's Minolira (minocycline) extended-release tablets to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.
    - This formulation of minocycline 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, Minolira should be used only as indicated.
    - Minolira will be manufactured by Dr. Reddy's and marketed by Promius Pharma.
- Minocycline is also available generically as immediate-release 50 mg, 75 mg, and 100 mg tablets and capsules, generically as extended-release 45 mg, 90 mg, and 135 mg tablets, brand-name extended-release 55 mg, 65 mg, 80 mg, 105 mg, and 115 mg tablets (Solodyn®) and as brand-name intravenous (IV) Minocin®.
- Immediate-release minocycline tablets and capsules and IV Minocin are indicated for the treatment of a variety of bacterial infections and as adjunctive therapy in acute intestinal amebiasis and severe acne (refer to drug labels for specific indications). Extended-release minocycline tablets and Solodyn have the same indication as Minolira.
- The safety and efficacy of Minolira in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris was assessed in two 12-week, double-blind, placebo-controlled trials in 924 patients ≥ 12 years of age. The primary efficacy endpoints were mean percent change in inflammatory lesion counts from baseline to 12 weeks and percentage of patients with an Evaluator's Global Severity Assessment of clear or almost clear at 12 weeks.
    - The mean percent improvement in inflammatory lesions was 43.1% and 45.8% for Minolira-treated patients vs. 31.7% and 30.8% in placebo-treated patients in trials 1 and 2, respectively.
    - The percentage of patients who were clear or almost clear was 17.3% and 15.9% in Minolira-treated patients vs. 7.9% and 9.5% in placebo-treated patients in trials 1 and 2, respectively.
    - Minolira did not demonstrate any effect on non-inflammatory lesions.
- Warnings and precautions of Minolira include teratogenic effects, tooth discoloration, inhibition of bone growth, pseudomembranous colitis, hepatotoxicity, metabolic effects, central nervous system effects, intracranial hypertension, autoimmune syndromes, photosensitivity, serious skin/hypersensitivity reaction, tissue hyperpigmentation, development of drug-resistant bacteria, superinfection, and laboratory monitoring.
- The most common adverse reactions (≥ 5%) with Minolira use were headache, fatigue, dizziness, and pruritus.
- The recommended dosage of Minolira is approximately 1 mg/kg once daily for 12 weeks.
    - Refer to Minolira's drug label for information about tablet strength and size to administer.
    - Higher doses have not shown to be of additional benefit in the treatment of inflammatory lesions of acne, and may be associated with more acute vestibular side effects.
    - Ingestion of food along with Minolira may help reduce the risk of esophageal irritation and ulceration.
    - Minolira tablets should not be chewed or crushed.

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- Promius Pharma's launch plans for Minolira are pending. Minolira will be available as 105 mg and 135 mg extended-release tablets.