Talicia® (omeprazole/amoxicillin/rifabutin) – New drug approval

- On November 4, 2019, RedHill Biopharma announced the FDA approval of Talicia (omeprazole/amoxicillin/rifabutin), for the treatment of *Helicobacter pylori (H. pylori)* infection in adults.

- In the U.S., an estimated 2.5 million patients are treated annually for *H. pylori* infection. It is the strongest risk factor for the development of gastric cancer and a major risk factor for peptic ulcer disease and gastric mucosa-associated lymphoid tissue lymphoma.

    - Current standard-of-care therapies fail in approximately 25% to 40% of patients who remain *H. pylori* positive due to growing resistance of *H. pylori* to clarithromycin and metronidazole, antibiotics commonly used in standard combination therapies.

- Talicia is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (omeprazole).

- The efficacy of Talicia was established in a randomized, double-blind, controlled study in 455 treatment-naïve *H. pylori*-positive adult patients complaining of epigastric pain/discomfort. Patients received Talicia or control (total daily dose of amoxicillin 3000 mg and omeprazole 120 mg) administered for 14 consecutive days. *H. pylori* eradication was confirmed with a negative ^{13}C urea breath test (UBT) or fecal antigen test performed ≥ 28 days post-therapy.

    - Successful *H. pylori* eradication was achieved in 83.8% and 57.7% of patients treated with Talicia or control, respectively ($p < 0.0001$).

- An additional placebo-controlled study of Talicia in *H. pylori*-positive adult patients was conducted and provided supportive evidence for the efficacy of Talicia. In 77 patients taking Talicia and 41 patients taking placebo, the eradication rate was 76.6% (95% CI: 66.0, 84.7) for the Talicia-treated patients vs. 2.4% for the placebo-treated patients.

- Talicia is contraindicated in patients with: known hypersensitivity to omeprazole, amoxicillin or any other beta-lactam antibacterial drugs, rifabutin or any other rifamycin, or any component of Talicia; and in patients with concomitant use of rilpivirine-containing products, delavirdine, or voriconazole.

- Warnings and precautions for Talicia include hypersensitivity reactions, *Clostridioides difficile* associated diarrhea, reduced efficacy of hormonal contraceptives, acute interstitial nephritis, risk of adverse reactions or loss of efficacy due to drug interactions, cutaneous and systemic lupus erythematosus, rash in patients with mononucleosis, uveitis, interactions with diagnostic investigations for neuroendocrine tumors, and development of drug-resistant bacteria.

- The most common adverse reactions (≥ 1%) with Talicia use were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

- The recommended dose of Talicia is four Talicia capsules every 8 hours for 14 days with food. Each dose (4 capsules) of Talicia includes rifabutin 50 mg, amoxicillin 1,000 mg and omeprazole 40 mg.

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- RedHill Biopharma plans to launch Talicia in the first quarter of 2020. Talicia will be available as a delayed-release capsule containing omeprazole 10 mg, amoxicillin 250 mg, and rifabutin 12.5 mg.