Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline) – New Boxed Warning

- On January 25, 2017, the FDA approved a new *Boxed Warning* to the Pylera (bismuth subcitrate potassium/metronidazole/tetracycline) drug label regarding the potential for carcinogenicity. Other safety updates were made to the *Contraindications*, *Warnings and Precautions*, and *Adverse Reactions* sections.

- Pylera in combination with omeprazole are indicated for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*. The eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence.

    - To reduce the development of drug-resistant bacteria and maintain the effectiveness of Pylera and other antibacterial drugs, Pylera should be used to treat only indicated infections that are proven or strongly suspected to be caused by susceptible bacteria.
    - When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

- The new *Boxed Warning* for Pylera states that metronidazole has been shown to be carcinogenic in mice and rats. It is unknown whether metronidazole is associated with carcinogenicity in humans.

    - Similar information was added to the *Warnings and Precautions* section.

- The *Contraindications* section was also updated with new information stating that Pylera Is contraindicated during pregnancy.

- Other new updates to the *Warnings and Precautions* section include increased plasma concentrations in patients with hepatic impairment, cutaneous reactions, and drug interactions with oral contraceptives, anticoagulants, lithium, and busulfan (Busulfex®, Myleran®).

- Additional new updates were made to the *Adverse Reactions* section including postmarketing information regarding peripheral neuropathy and skin and subcutaneous disorders. The Pregnancy and Lactation subsection was updated to align with current FDA drug labeling requirements.