Konvomep™ (omeprazole/sodium bicarbonate) – New drug approval

- On August 30, 2022, the FDA approved Azurity Pharmaceuticals' Konvomep (omeprazole/sodium bicarbonate) for oral suspension, in adults for: short-term treatment (4 to 8 weeks) of active benign gastric ulcer and reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients.

- Omeprazole/sodium bicarbonate capsules are available over-the-counter and an omeprazole/sodium bicarbonate powder for oral suspension is available as a prescription generically. The other oral suspension is approved for reduction of risk of upper GI bleeding in critically ill adult patients.

- The effectiveness of Konvomep has been established, in part, based on studies of an oral delayed-release omeprazole product for the treatment of active benign gastric ulcer. Additionally, the effectiveness has been established, in part, based on studies of another omeprazole and sodium bicarbonate oral suspension product for the reduction of risk of upper GI bleeding in critically ill adult patients.

- Konvomep is contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any components of the Konvomep formulation and in patients receiving rilpivirine containing products.

- Warnings and precautions for Konvomep include presence of gastric malignancy; acute tubulointerstitial nephritis; sodium content; *Clostridium difficile*-associated diarrhea; bone fracture; severe cutaneous adverse reactions; cutaneous and systemic lupus erythematosus; interaction with clopidogrel; cyanocobalamin (vitamin B-12) deficiency; hypomagnesemia and mineral metabolism; interaction with St. John's wort or rifampin; interactions with investigations for neuroendocrine tumors; interaction with methotrexate; and fundic gland polyps.

- The most common adverse reactions (≥ 2%) with Konvomep use were headache, abdominal pain, nausea, diarrhea, vomiting, and flatulence.

- The recommended dosage of Konvomep is based upon the omeprazole content of Konvomep. For treatment of benign gastric ulcer, the recommended dosage of Konvomep is 40 mg once daily for a treatment duration of 4 to 8 weeks. For reduction of risk of upper GI bleeding in critically ill patients, the recommended dosage is 40 mg initially; followed by 40 mg 6 to 8 hours later; and 40 mg once daily thereafter; for a treatment duration of 14 days.

    — Konvomep is a kit of two bottles: one bottle containing omeprazole powder and one bottle of diluent containing sodium bicarbonate. Konvomep is for reconstitution by a healthcare provider for use in adults.

- Azurity Pharmaceuticals' launch plans for Konvomep are pending. Konvomep will be available as 2 mg omeprazole and 84 mg sodium bicarbonate per mL after reconstitution in 90 mL, 150 mL, or 300 mL bottles.