FOR IMMEDIATE RELEASE

AMNEAL LAUNCHES ESOMEPRAZOLE STRONTIUM 49.3 mg DELAYED-RELEASE CAPSULES, A PHARMACEUTICAL ALTERNATIVE TO NEXIUM®

New GERD treatment for adults is now available

Bridgewater, NJ (USA), December 17, 2013 – Amneal Pharmaceuticals LLC today announced the launch of its branded Esomeprazole Strontium 49.3 mg delayed-release capsules. Esomeprazole Strontium contains the same active moiety (esomeprazole) in a different salt form as found in the branded proton-pump inhibitor Nexium® (esomeprazole magnesium) and is a new option for adult patients for the short term treatment of gastroesophageal reflux disease (GERD). Amneal is marketing the 505(b)(2) product in the United States under an exclusive license and distribution agreement with Hanmi Pharmaceutical Co. Ltd of South Korea.

Each 49.3 mg strength Esomeprazole Strontium capsule provides the equivalent of 40 mg of esomeprazole base – an equivalent amount of esomeprazole that is present in the corresponding Nexium® dose. Esomeprazole Strontium capsules are offered in 30-count bottles.

Manufactured in the United States, Esomeprazole Strontium will start shipping Wednesday, December 18th through the three major U.S. pharmaceutical wholesalers.

Important Safety Information for Esomeprazole Strontium 49.3 mg delayed-release capsules

Indications and Usage

Esomeprazole Strontium is a proton pump inhibitor (PPI) indicated for adults for:

- Treatment of gastroesophageal reflux disease (GERD)
- Risk reduction of NSAID-associated gastric ulcer
- H. pylori eradication to reduce the risk of duodenal ulcer recurrence
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome

The safety and effectiveness of esomeprazole strontium have not been established in pediatric patients. Esomeprazole strontium is not recommended for use in pediatric patients.

The safety of esomeprazole strontium has not been studied in patients with severe renal impairment. Esomeprazole strontium is not recommended for use in patients with severe renal impairment.

Nursing mothers should consider discontinuing esomeprazole strontium.

There are no studies in pregnant women. Esomeprazole Strontium should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

Important Safety Information

Esomeprazole strontium is contraindicated in patients with known hypersensitivity to PPIs. Hypersensitivity reactions, e.g., angioedema and anaphylactic shock have been reported with esomeprazole use.

Symptomatic response to therapy does not preclude the presence of gastric malignancy.

Atrophic gastritis has been noted occasionally in biopsies from patients treated long-term with omeprazole.

PPI therapy may be associated with increased risk of Clostridium difficile associated diarrhea.

Avoid concomitant use of esomeprazole strontium with clopidogrel, because the metabolism of clopidogrel can be impaired. When using esomeprazole strontium consider alternative anti-platelet therapy.

Long-term and multiple daily dose PPI therapy may be associated with an increased risk of osteoporosis-related fractures of the hip, wrist, or spine.

Hypomagnesemia has been reported rarely with prolonged treatment with PPIs. Serious events included tetany, arrhythmias, and seizures, and may require discontinuation of the PPI.

Most common adverse reactions in adults (≥18 years) (incidence ≥1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth.

Avoid concomitant use of esomeprazole strontium with drugs which induce CYP2C19 or CYP3A4, such as with St. John's wort or rifampin, due to the potential substantial reduction in esomeprazole levels.

Patients treated with PPIs and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time. Esomeprazole may interfere with the absorption of drugs for which gastric pH affects bioavailability (e.g., ketoconazole, iron salts, and digoxin).

Drug-induced decreases in gastric acidity may increase serum chromogranin A (CgA) levels and may cause false positive results in diagnostic investigations for neuroendocrine tumors. Providers should temporarily stop esomeprazole treatment before assessing CgA levels.

Concomitant use with atazanavir and nelfinavir is not recommended; Concomitant use of saquinavir with PPIs is expected to increase saquinavir concentrations, which may increase toxicity.

Click **here** to see full prescribing information.

About Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC is a U.S.-based manufacturer of generic pharmaceuticals. Known as "Generic's New Generation", Amneal prides itself on its unwavering commitment to quality, meaningful business relationships, and innovative approach to maximizing value for all stakeholders. Extensive investment in R&D, an intelligently aggressive expansion strategy, and focus on vertical integration are key contributors to the company's impressive growth over the past several years. Amneal is headquartered in Bridgewater, New Jersey with manufacturing, R&D, packaging, sales and distribution facilities throughout the U.S., as well as abroad. For more information, visit www.amneal.com.

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