FOR IMMEDIATE RELEASE

First FDA-Approved 100 mg Thiotepa Now Available through Amneal Biosciences as TEPADINA® (thiotepa) for Injection

Bridgewater, NJ (USA), April 27, 2017 – Thiotepa is now available through Amneal Biosciences in both 100 mg/vial and 15 mg/vial as branded TEPADINA® (thiotepa) for injection. The product is supplied as a powder for solution in single-dose vials for intravenous, intracavitary, or intravesical use.

As the exclusive U.S. distributor for TEPADINA®, Amneal Biosciences began shipping the branded thiotepa today from its distribution center in Kentucky. The product is available for purchase through major wholesalers and distributors.

TEPADINA® is approved to reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia. In addition, the product is approved for the same oncologic indications as generic thiotepa.

TEPADINA® may cause severe marrow suppression, and high doses may cause marrow ablation with resulting infection or bleeding. Hematopoietic progenitor (stem) cell transplantation (HSCT) is required to prevent potentially fatal complications of the prolonged myelosuppression after high doses of TEPADINA®. TEPADINA® should be considered potentially carcinogenic in humans. It is contraindicated in patients with severe hypersensitivity to thiotepa and in concomitant use with live or attenuated vaccines. The most common adverse reactions are neutropenia, anemia, thrombocytopenia, elevated alanine aminotransferase, elevated aspartate aminotransferase, elevated bilirubin, mucositis, cytomegalovirus infection, hemorrhage, diarrhea, hematuria and rash.

Visit http://www.amneal.com/thiotepa-pi for full prescribing information including boxed warning and important safety information for TEPADINA®.

“The introduction of 100 mg thiotepa provides pharmacists with a convenient choice of sizes to accommodate larger doses,” explains Amneal Biosciences President, Charles Lucarelli. “We are thrilled to bring to the U.S. a product that is not only valuable to the pediatric transplant process, but in the 100 mg vial that’s been unavailable for years. Now we have a fully FDA-approved thiotepa molecule with options for the reconstituting pharmacist.”

Amneal Biosciences brings TEPADINA® to the U.S. market on behalf of NDA-holder ADIENNE SA. “This exclusive distribution partnership with ADIENNE further demonstrates Amneal’s ability to successfully commercialize complex products in the U.S.,” says Amneal VP of Global Strategy and Corporate Development, Apurva Saraf. “We continue to pursue such strategic partnerships to complement our expansive and diverse internal pipeline.”

About Amneal

Amneal Biosciences LLC, a wholly-owned subsidiary of Amneal Pharmaceuticals LLC, is dedicated to the commercialization of high-barrier-to-entry generic and specialty pharmaceuticals such as injectables, oncologics, anti-infectives and support care for healthcare providers and patients of all ages. The company’s expertise and focus on the unique needs and logistics of this market ensure the same level of quality and service for healthcare institutions and professionals that Amneal delivers to its retail customers.

Amneal Pharmaceuticals LLC, a privately-held company headquartered in Bridgewater, New Jersey, is one of the largest and fastest growing generic pharmaceutical manufacturers in the United States. Founded in 2002, Amneal now has more than 4,500 employees in its operations in North America, Asia, Australia and Europe, working together to bring high-quality, affordable medicines to patients worldwide.

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