FOR IMMEDIATE RELEASE

AMNEAL PHARMACEUTICALS RECEIVES FDA APPROVAL FOR GENERIC SUBOXONE®

Buprenorphine HCl and Naloxone HCl tablets for treating opioid addiction expected to save millions in healthcare costs

Bridgewater, NJ (USA), February 25, 2013 – Amneal Pharmaceuticals, LLC, the 7th largest generic drug manufacturer in the U.S. market, has received U.S. FDA approval for one of the first generic versions of Suboxone® sublingual tablets for maintenance treatment of opioid drug dependence. Generic buprenorphine hydrochloride (HCl) and naloxone HCl dihydrate sublingual tablets are now available in 2 mg/0.5 mg and 8 mg/2 mg strengths, both in 30-count bottles. The Amneal medication is bioequivalent to Suboxone® (a registered trademark of Reckitt Benckiser Healthcare (UK) Limited). Annual U.S. sales of Suboxone® in all dosage forms are $1.5 billion, according to December 2012 IMS Health market data.

Providing opioid-dependent patients with high quality generic buprenorphine HCl and naloxone HCl through treatment in physicians' offices, treatment centers, or prescriptions filled at retail pharmacies offers tremendous cost savings for both consumers and the U.S. healthcare system, while delivering the same therapeutic effect as the brand medication. To help their patients take advantage of this lower cost alternative, physicians should clearly indicate "buprenorphine HCl and naloxone HCl tablets" or "Suboxone® tablets" when writing prescriptions to avoid confusion at the pharmacy. Patients currently using any form of Suboxone® should ask their doctors or dispensing pharmacists for buprenorphine HCl and naloxone HCl sublingual tablets to get the cost-saving generic version with a pleasant orange flavor.

In addition to patients and their prescribing physicians, a more cost-effective opioid addiction treatment should be welcome news to insurance companies, the Centers for Medicare and Medicaid Services, the Veterans Health Administration and other payors, pharmacy benefits managers (PBMs), managed care facilities, drug addiction and recovery organizations and treatment advocacy groups as well. Generic drugs are saving the U.S. healthcare system one billion dollars every other day, according to the Generic Pharmaceutical Association.

"The FDA's decision to approve the first generic equivalents to Suboxone® sublingual tablets will ensure that millions of patients in the U.S. who need this product now have access to a high quality, low cost generic version," said Chirag Patel, President and Co-Chairman of Amneal. "Since the agency has issued its opinion on Reckitt Benckiser's September 2012 Citizen's Petition in favor of generic competition, Amneal's buprenorphine HCl and naloxone HCl tablets can offer consumers and physicians greater choice in opioid addiction treatment. We are also pleased that the FDA has referred this matter to the Federal Trade Commission to investigate and address Reckitt's anticompetitive business practices."

"We appreciate the FDA's thorough assessment of Reckitt's Citizen's Petition and applaud their recent decision to deny it in its entirety," said Chintu Patel, Amneal CEO and Co-Chairman. "The FDA determined that Reckitt's petition did not raise valid scientific or regulatory issues associated with the product, which Amneal contended in its comments on the petition. Physicians should have no concerns in writing prescriptions for the generic tablet form of the product."

Manufactured in Amneal's fully FDA-compliant Brookhaven, NY facility, buprenorphine HCl and naloxone HCl tablets will be available through wholesalers and distributors as well as directly to the trade. The product received FDA approval under an approved Risk Evaluation and Mitigation Strategy (REMS), known as the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS program, and will be distributed in accordance with FDA and U.S. Drug Enforcement Administration (DEA) regulations governing the handling of CIII controlled substances. The generic tablets will be available to patients when the BTOD REMS program becomes operational in early March.

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 amneal.com.

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