





Amneal Launches Methylphenidate Hydrochloride Extended-Release Tablets, USP (CII) AB-Rated Generic for Concerta®

Bridgewater, NJ (USA), February 5, 2018 - <u>Amneal Pharmaceuticals</u> has launched methylphenidate hydrochloride extended-release tablets, USP (CII) in 18, 27, 36, and 54 mg strengths.

Amneal's methylphenidate is an AB-rated equivalent to the brand Concerta[®]. The Amneal ANDA included all bioequivalence metrics recommended by FDA.

"We are extremely pleased to add our methylphenidate to the list of therapeutically equivalent generics for Concerta," commented Amneal EVP - Sales & Marketing Jim Luce. "The entrance of another AB-rated option adds to the choices provided patients, prescribers and payers beyond non-substitutable BX-rated products and the brand."

Methylphenidate hydrochloride ER tablets are now shipping to wholesalers, distributors and direct to the trade. All strengths are available in 90-ct bottles with a 30-ct size available upon request. The product is manufactured in the U.S.A. at the Amneal plant in Brookhaven, New York.

Annual U.S. sales of methylphenidate ER were \$1.5 billion, according to December 2017 IQVIA® market data.

Click here for full prescribing information, including boxed warning and important safety considerations.

About Amneal

Amneal Pharmaceuticals LLC, a privately-held company headquartered in Bridgewater, New Jersey, is one of the largest and the fastest growing generics pharmaceutical manufacturers in the United States. Founded in 2002, Amneal now has more than 5,000 employees in North America, Asia and Europe, working together to bring high quality affordable medicines to patients worldwide. Amneal has significantly expanded its portfolio of generic products to include complex dosage forms in a broad range of therapeutic areas.

Amneal Pharmaceuticals LLC and Impax Laboratories, Inc. (NASDAQ: IPXL) announced on October 17, 2017 that they have entered into a definitive business combination agreement with the resulting combined company expected to create the 5th largest generics business (by gross revenue) in the United States. The transaction is expected to close in the first half of 2018.

For more information, visit amneal.com.

All trademarks listed in this release are property of their respective owners. Product photo is available upon request.

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CONTACTS:

Sales

Jim Luce (sales)
Executive Vice President, Sales & Marketing
949.432.1389
jim.luce@amneal.com

Media

Cheryl Lechok 203.613.1506 mediarelations@amneal.com

Business Development

Apurva Saraf Vice President, Global Strategy & Corporate Development Amneal Pharmaceuticals 631.742.7674 apurvas@amneal.com