Amphastar Announces Approval for Isoproterenol Hydrochloride Injection, USP

June 19, 2018

RANCHO CUCAMONGA, Calif., June 19, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration (“FDA”) has granted approval of its abbreviated new drug application (“ANDA”) for Isoproterenol Hydrochloride Injection, USP 0.2mg/mL, 1mL and 0.2mg/mL, 5mL single dose vial. Isoproterenol Hydrochloride is indicated for multiple uses including for mild or transient episodes of heart block that do not require electric shock or pacemaker therapy. Amphastar’s newly approved product was determined by the FDA to be therapeutically equivalent to Isuprel® (Isoproterenol Hydrochloride Injection) sold in the United States by Valeant Pharmaceuticals.

Amphastar's CEO, Dr. Jack Zhang, stated: "We are excited about the FDA approval of Isoproterenol Hydrochloride Injection, which currently only has one other generic vial in the market. This approval further strengthens our vertical integration strategy, given that the Active Pharmaceutical Ingredient for this product is manufactured by Amphastar Nanjing Pharmaceuticals, Co., Ltd., our subsidiary in China."

According to IQVIA, U.S. brand and generic sales of Isoproterenol Hydrochloride Injection, 0.2 mg/mL, 1mL and 0.2mg/mL, 5mL vials and ampules were approximately $147 million for the 12 months ended March 31, 2018.

Amphastar anticipates launching its product in the third quarter of 2018.

Pipeline Information

The Company currently has two ANDAs filed with the FDA, which are targeting products with a market size of over $0.35 billion, three biosimilar products in development targeting products with a market size of $15.0 billion, and 12 generic products in development targeting products with a market size of over $12.0 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2018. The Company’s proprietary pipeline includes NDAs for Primatene® Mist and intranasal naloxone. The Company is currently developing several other proprietary products with various dosage forms.

Company Information

Amphastar is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable and inhalation products. Additionally, the Company sells insulin API products. Most of the Company’s finished products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. More information is available at the Company’s website at www.amphastar.com.

Forward Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to the Company's expectations regarding litigation matters, collection of the bond posted by the Plaintiffs and other matters related to its current products, pipeline of product candidates and other future events. These statements are not historical facts but rather are based on Amphastar's current expectations, estimates, and projections regarding Amphastar's business, operations, and other similar or related factors. Words such as "may," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expects," "intends," "plans," "projects," "believes," "estimates," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Amphastar's control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Amphastar's filings with the Securities and Exchange Commission. Amphastar undertakes no obligation to revise or update information in this press release to reflect events or circumstances in the future, even if new information becomes available.

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