Amphastar Pharmaceuticals, Inc. Receives FDA Approval for Epinephrine Injection, USP 30mg/30mL (1mg/mL) Multiple Dose Vial

April 27, 2020

RANCHO CUCAMONGA, Calif., April 27, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ: AMPH) ("Amphastar"), today announces that the U.S. Food and Drug Administration ("FDA") has granted approval of its Abbreviated New Drug Application ("ANDA") for Epinephrine Injection, USP 30mg/30mL (1mg/mL) Multiple Dose Vial. Amphastar's newly approved drug product was determined by the FDA to be therapeutically equivalent to Adrenalin® (Epinephrine Injection, USP 30mg/30mL (1mg/mL) Multiple Dose Vial) distributed in the United States by Par Pharmaceutical, Inc. Epinephrine Injection Multiple Dose Vial is for intramuscular, subcutaneous, and intravenous use, and is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis, and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

Additionally, the FDA granted 180 day exclusivity to Amphastar as the first generic filer.

Amphastar's CEO and President, Dr. Jack Zhang, commented: "We are pleased about the FDA's approval of our Epinephrine Injection Multiple Dose Vial, which currently does not have any generic equivalent in the market. This approval expands the product offerings in our generic critical care injectable portfolio and highlights our commitment and internal capability of bringing generic injectable products to the market."

According to IQVIA™, U.S market annual sales for the 12 months ended December 31, 2019 for Epinephrine Injection, 30mg/30mL (1mg/mL) Multiple Dose Vial was approximately $ 131 million.

Amphastar plans to launch this Epinephrine Injection Multiple Dose Vial within two to three months.

Pipeline Information

The Company currently has six ANDAs filed with the FDA, which are targeting products with a market size of approximately $1.8 billion, three biosimilar products in development targeting products with a market size of approximately $13 billion, and nine generic products in development targeting products with a market size of approximately $12 billion. This market information is based on IQVIA data for the 12 months ended December 31, 2019. The Company is developing multiple proprietary pipeline products for injectable and intranasal dosage forms, including a new drug application for intranasal naloxone.

Amphastar's Chinese subsidiary, ANP, currently has 14 Drug Master Files, or DMF, on file with the FDA and is developing several additional DMFs.

Company Information

Amphastar is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable,

inhalation, and intranasal 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 and resources are available 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 future financial performance, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to its pipeline of product candidates, its share buyback program and other future events. These statements are not historical facts but rather are based on Amphastar's historical performance and its current expectations, estimates, and projections regarding Amphastar's business, operations and other similar or related factors. Words such as "may," "might," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," 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. You can locate these reports through the Company's website at http://ir.amphastar.com and on the SEC's website at www.sec.gov. 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 or if subsequent events cause Amphastar's expectations to change.

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