Amphastar Announces Approval for Neostigmine Methylsulfate Injection, USP

September 25, 2017

RANCHO CUCAMONGA, Calif., Sept. 25, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration ("FDA") granted approval of its abbreviated new drug application (ANDA) for Neostigmine Methylsulfate Injection, USP, 1mg/mL, 10mL, and 0.5mg/mL, 10mL vial. Amphastar's newly approved product was determined by the FDA to be therapeutically equivalent to Bloxiverz® sold in the United States by Avadel, with the same active ingredients, route of administration, strength and dosage form.

Amphastar's CEO, Dr. Jack Zhang, stated: "We are excited about the approval of Neostigmine Methylsulfate Injection, which expands the product offerings of our generic injectable portfolio."

According to IMS Health data, U.S. brand and generic sales of Neostigmine Methylsulfate Injection, USP, 1mg/mL, 10mL, and 0.5mg/mL, 10 mL were approximately $185 million for the 12 months ended June 30, 2017.

Amphastar anticipates launching its product in the fourth quarter of 2017.

Pipeline Information

The Company currently has five abbreviated new drug applications, or ANDAs filed with the FDA, targeting products with a market size of over $0.9 billion, three biosimilar products in development targeting products with a market size of $15.0 billion, and 11 generic products in development targeting products with a market size of over $12.0 billion. This market information is based on IMS Health data for the 12 months ended June 30, 2017. The Company's proprietary pipeline includes NDAs for Primatene® Mist and intranasal naloxone. The Company is currently developing other proprietary products, which include injectable, inhalation and intranasal 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. In 2014, the Company also commenced sales of insulin active pharmaceutical ingredient 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 regulatory filings or approvals 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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