Amphastar Pharmaceuticals, Inc. Announces Reintroduction of Primatene® MIST

November 8, 2018

Primatene® MIST fills unmet medical need as the only FDA approved over-the-counter asthma inhaler

Primatene Mist

RANCHO CUCAMONGA, Calif., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ: AMPH) announced today that the U.S. Food and Drug Administration (FDA) granted approval of its New Drug Application (NDA) for Primatene® MIST (epinephrine inhalation aerosol bronchodilator suspension), which is delivered by a metered dose inhaler (MDI) with a non-chlorofluorocarbon (CFC) propellant. Primatene® MIST is the only FDA-approved asthma inhaler available without a prescription in the United States. Primatene® MIST is indicated for the temporary relief of mild symptoms of intermittent asthma in people ages 12 and above.

Amphastar's CEO, Dr. Jack Zhang, stated: "We are very happy to have received FDA approval for Primatene® MIST and are proud to bring this important product back to the over-the-counter (OTC) market in the United States. We are grateful to the FDA team for working closely with us to make this approval possible, recognizing the important role of OTC bronchodilator drugs such as Primatene® MIST. Amphastar's mission is to develop and bring to market innovative pharmaceutical products and delivery systems that will meaningfully improve peoples' lives and we believe Primatene® MIST will do just that."

The newly approved, patented formulation of Primatene® MIST is made with the same active ingredient, epinephrine, which was used in the original Primatene® Mist before it was removed from the market in 2011 for environmental reasons pursuant to the Montreal Protocol, an important international environmental treaty, which phased out products worldwide containing ozone-depleting CFCs. The product's new inhalation delivery system no longer includes CFC as the propellant and has other significant new features, including a built-in spray indicator and a metal canister, which replaces the glass container used in the original Primatene® Mist product.

According to the Centers for Disease Control and Prevention National Center for Health Statistics, approximately 20 million adults in the United States suffer from asthma. Amphastar is pleased to bring back Primatene® MIST as an OTC option for the temporary relief of mild symptoms of intermittent asthma. For more information, visit www.Primatene.com.

Amphastar anticipates that Primatene® MIST will be available in major drug stores across the United States in early 2019.

Pipeline Information

The Company currently has four abbreviated new drug applications ("ANDAs") filed with the FDA, which are targeting products with a market size of approximately $0.7 billion, three biosimilar products in development targeting products with a market size of approximately $14.0 billion, and 11 generic products in development targeting products with a market size of approximately $12.0 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2018. The Company's proprietary pipeline includes an NDA for intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

Company Information

Amphastar is a specialty pharmaceutical company that focuses on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable, inhalation and intra-nasal 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 future financial performance, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including DMFs, the timing of product launches and the timing of products becoming available on the market, acquisitions 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 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," "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. 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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A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/a8f641c2-1af8-45c6-8087-ef498ee5af49

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