Amphastar Announces the Receipt of a MINOR CRL for Epinephrine Injection, USP 30mg/30mL (1mg/mL) Multiple Dose Vial

January 28, 2020

RANCHO CUCAMONGA, Calif., Jan. 28, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ: AMPH) announced that on January 24, 2020, the U.S. Food and Drug Administration ("FDA") issued a "**MINOR**" Complete Response Letter ("CRL") for its Abbreviated New Drug Application ("ANDA") for Epinephrine Injection, USP 30mg/30mL (1mg/mL) Multiple Dose.

Amphastar responded to the MINOR CRL on January 27, 2020, and expects a decision from the FDA within three months.

Pipeline Information

The Company currently has five ANDAs, filed with the FDA targeting products with a market size of approximately $1.1 billion, three biosimilar products in development targeting products with a market size of approximately $13 billion, and 11 generic products in development targeting products with a market size of approximately $13 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2019. The Company's proprietary pipeline includes a new drug application for intranasal naloxone. The Company is currently developing three other proprietary products, which include injectable 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, 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. Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Primatene®, Amphadase® and Cortrosyn®, are the property of Amphastar.

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 or the conference call referenced above 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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