

Amphastar Pharmaceuticals Receives FDA Approval for Supplement to its Abbreviated New Drug Application for Sodium Bicarbonate Injection, USP 8.4%, 50mEq/50mL

February 27, 2020

RANCHO CUCAMONGA, Calif., Feb. 27, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) announced today that the U.S. Food and Drug Administration (“FDA”) granted approval of its supplemental Abbreviated New Drug Application for Sodium Bicarbonate Injection, USP, 8.4%, 50mEq/50mL (1mEq/mL) Single-Dose Prefilled Syringe. This supplement is for manufacturing the product in the Company’s new manufacturing line at its International Medication Systems facility.

Amphastar’s CEO, Dr. Jack Zhang, commented: “We are very pleased with the FDA’s approval, which will allow us to start manufacturing in our new state-of-the-art production line. This approval significantly increases our manufacturing capacity, which will help alleviate the shortages of the critical care injectable products. It is also helpful for our pipeline projects, which will be produced on the new line. We recognize the great importance of the availability of emergency syringes for public health and the need for a reliable and consistent supply. This approval further validates our strength in scaling up our manufacturing capabilities in response to increased demand for our products.”

Pipeline Information

The Company currently has seven Abbreviated New Drug Applications filed with the FDA, which are targeting products with a market size of approximately \$1.9 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 also developing four injectable and intranasal proprietary products, which include a new drug application for intranasal naloxone.

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[®] Mist, 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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