Amphastar Pharmaceuticals, Inc. Receives FDA Approval for Succinylcholine Chloride Injection USP, 200 mg/10 mL (20 mg/mL) Multiple-Dose Vial

June 9, 2020

RANCHO CUCAMONGA, Calif., June 09, 2020 (GLOBE NEWSWIRE) -- Amphastar® Pharmaceuticals, Inc., (NASDAQ: AMPH) ("Amphastar"), today announces that the U.S. Food and Drug Administration ("FDA") has approved its Abbreviated New Drug Application ("ANDA") for Succinylcholine Chloride Injection USP, 200 mg/10 mL (20 mg/mL) Multiple-Dose Vial. Amphastar's newly approved drug product was determined by the FDA to be therapeutically equivalent to Quelicin™ (Succinylcholine Chloride Injection USP, 200 mg/10 mL (20 mg/mL) Multiple-Dose Vial) distributed in the United States by Pfizer, Inc. Succinylcholine Chloride Injection is for intramuscular and intravenous use. It is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Amphastar's CEO and President, Dr. Jack Zhang, commented: "We would like to thank the FDA review team for working diligently and approving this application in its first review cycle. This approval highlights the strengths of our quality systems and regulatory capabilities in pipeline development."

According to IQVIA™, U.S market annual sales for the 12 months ended March 31, 2020 for Succinylcholine Chloride Injection USP, 200 mg/10 mL (20 mg/mL) Multiple-Dose Vial was approximately $75 million.

Pipeline Information

The Company currently has five ANDAs filed with the FDA, which are targeting products with a market size of approximately $1.7 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 March 31, 2020. 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.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar®, 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. However, 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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