

Amphastar Pharmaceuticals Receives FDA Approval for Calcium Chloride Injection

May 14, 2018

RANCHO CUCAMONGA, Calif., May 14, 2018 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration (“FDA”) granted approval of the company’s abbreviated new drug application (“ANDA”) for Calcium Chloride injection 10% in the 10 mL Luer-Jet[®] Prefilled Syringe System. For the past 40 years, the company has sold and marketed the product under the “grandfather” exception (now termed “unapproved”) to the FDA’s “Prescription Drug Wrap-Up” program. Net revenues for the company’s Calcium Chloride injection for the year ended December 31, 2017 were \$13.5 million.

Amphastar's CEO, Dr. Jack Zhang, stated: "We are pleased about the FDA’s approval of our Calcium Chloride injection which continues to demonstrate our commitment to work with the Agency to alleviate drug shortages."

The company continues to market four unapproved products, and has two ANDAs and one NDA pending approval for these products. For the year ended December 31, 2017, the company recorded net revenues of \$22.0 million from unapproved products.

Pipeline Information

The Company currently has three ANDAs filed with the FDA, which are targeting products with a market size of over \$0.5 billion of three biosimilar products in development with a market size of \$15.0 billion; 12 generic products in development targeting products with a market size of over \$12.0 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2018. The Company’s proprietary pipeline includes NDAs for Primatene[®] Mist and intranasal naloxone. The Company is currently developing several other proprietary products with various 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. 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.

Amphastar’s logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene[®], Amphadase[®] and Cortrosyn[®], are the property of Amphastar Pharmaceuticals, Inc.

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 litigation matters, collection of the bond posted by the Plaintiffs 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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