



September 20, 2017

Amphastar Pharmaceuticals Receives FDA Approval for Sodium Bicarbonate Injection

RANCHO CUCAMONGA, Calif., Sept. 20, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) announced that on September 19, 2017, the U.S. Food and Drug Administration ("FDA") granted approval of the company's abbreviated new drug application ("ANDA") for Sodium Bicarbonate injection 8.4% in the 50 mL Luer-Jet[®] Prefilled Syringe System. For the past 40 years, the company has sold and marketed the product under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. Net revenues for the company's sodium bicarbonate injection for the year ended December 31, 2016 were \$5.9 million.

The company continues to market five grandfathered products, (now termed "unapproved") and has ANDAs pending approval for three of these products. For the year ended December 31, 2016, the company recorded net revenues of \$27.6 million from these unapproved products.

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. In 2014, the Company also commenced sales of insulin active pharmaceutical ingredient 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 regulatory filings or approvals 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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