February 21, 2017

Amphastar Announces the Receipt of a CRL for Intranasal Naloxone for the Emergency Treatment of Opioid Overdose

RANCHO CUCAMONGA, Calif., Feb. 21, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ:AMPH) announced today that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") for its New Drug Application ("NDA") for Naloxone Hydrochloride 2mg/0.5mL Nasal Spray ("Intranasal Naloxone"), indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

The CRL identifies issues including user human factors study, device evaluation, and other items that need to be addressed before the NDA can be approved.

Amphastar's CEO, Dr. Jack Zhang, stated: "While we are disappointed to have not received approval at this time, we intend to continue to work with the FDA to address their concerns in the CRL and hope to bring Intranasal Naloxone to the market as soon as possible."

Deaths from prescription opioids have more than quadrupled since 1999. From 2000 to 2015 more than half a million people died from drug overdoses. 91 Americans die every day from an opioid overdose.

Amphastar will continue to offer naloxone in pre-filled syringes while we pursue the NDA 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 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 sales and marketing of its products, the timing of FDA filings and other matters related to its 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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