

Amphastar Pharmaceuticals Receives FDA Approval for Morphine Sulfate Injection

May 3, 2021

RANCHO CUCAMONGA, Calif., May 03, 2021 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (NASDAQ: AMPH) announced that the U.S. Food and Drug Administration (“FDA”) approved the Company’s Abbreviated New Drug Application (“ANDA”) for Morphine Sulfate injection 1mg/mL in the 30mL Pump-Jet[®] Prefilled Syringe System. It is indicated for the management of pain severe enough to require use of an opioid analgesic by Patient-Controlled Analgesia (PCA), only for use with a compatible Alaris[®] infusion device, and for which alternative treatments are inadequate. For the past 30 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 Morphine injection for the year ended December 31, 2020, were \$2.3 million.

Amphastar’s CEO and President, Dr. Jack Zhang, commented: “The FDA’s approval of Morphine injection shows the Company’s continued commitment and ability to manufacture high quality injection products.”

Pipeline Information

The Company currently has five ANDAs on file with the FDA targeting products with a market size of approximately \$2.4 billion, three biosimilar products in development targeting products with a market size of approximately \$13 billion, and seven generic products in development targeting products with a market size of approximately \$10 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2021. The Company is currently developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar’s Chinese subsidiary, ANP, currently has 17 Drug Master Files, or DMFs, on file with the FDA and is developing several additional DMFs.

Company Information

Amphastar is a bio-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 Mist[®], Amphadase[®], and Cortrosyn[®], are the property of Amphastar.

Forward-Looking Statements

All statements in this press release and in the conference call referenced above 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, product development, 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, such as the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. 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, including in the Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 15, 2021. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time. 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. The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information or any forward-looking statements 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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