

# Amphastar Pharmaceuticals Receives FDA Approval for Atropine Sulfate Injection

October 6, 2020

RANCHO CUCAMONGA, Calif., Oct. 06, 2020 (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 Atropine Sulfate injection 0.1mg/mL in the 10 mL Luer-Jet<sup>®</sup> 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 Atropine Sulfate injection for the year ended December 31, 2019 were \$12.2 million.

Amphastar’s CEO and President, Dr. Jack Zhang, commented: “The FDA’s approval of our Atropine Sulfate product, a product often on the Agency’s Drug Shortage list, offers an opportunity to ensure quality products are produced at the highest standard and highlights Amphastar’s manufacturing capacity to fulfill such market needs.”

## Pipeline Information

The Company currently has four ANDAs filed with the FDA, which are targeting products with a market size of approximately \$1.5 billion, three biosimilar products in development targeting products with a market size of approximately \$13.0 billion, and nine generic products in development targeting products with a market size of approximately \$12.0 billion. This market information is based on IQVIA data for the 12 months ended June 30, 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](http://www.amphastar.com).

Amphastar’s logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar<sup>®</sup>, Primatene Mist<sup>®</sup>, Amphadase<sup>®</sup>, and Cortrosyn<sup>®</sup>, 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](http://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.

Noted products are trademarks or registered trademarks of their respective owners.

Contact Information:

Amphastar Pharmaceuticals, Inc.

Bill Peters

Chief Financial Officer

(909) 980-9484

Source: Amphastar Pharmaceuticals, Inc.