

Amphastar Pharmaceuticals Receives FDA Approval for Naloxone Hydrochloride Nasal Spray 4mg

March 8, 2023

RANCHO CUCAMONGA, CA / ACCESSWIRE / March 8, 2023 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) ("Amphastar" or the "Company") announced that the U.S. Food and Drug Administration ("FDA") has granted approval of its New Drug Application ("NDA") for naloxone hydrochloride nasal spray 4mg, which is delivered utilizing the Company's proprietary nasal delivery device. Naloxone hydrochloride nasal spray 4mg is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adult and pediatric patients.

Dr. Jack Zhang, Amphastar's President and Chief Executive Officer commented: "The approval of our naloxone hydrochloride nasal spray marks an important step in helping alleviate the opioids crisis as patients can further broaden their access to a critical product. Utilizing our innovative device platform, the approval of naloxone hydrochloride nasal spray validates our technical capabilities as we can leverage this towards our intranasal pipeline."

According to IQVIA, the U.S. sales of naloxone hydrochloride nasal spray 4mg in 2022 was approximately \$250 million for the 12 months ended December 31, 2022.

Pipeline Information

The Company currently has three ANDAs on file with the FDA targeting products with a market size of over \$3 billion, three biosimilar products in development targeting products with a market size of over \$11 billion, and six generic products in development targeting products with a market size of over \$9 billion. This market information is based on IQVIA data for the 12 months ended December 31, 2022. The Company is 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 referenced above that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, our future growth, backlog, sales and marketing of our products, market size and expansion, 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 our pipeline of product candidates, the timing and results of clinical trials, our share buyback program, and other future events, such as the impact of the COVID-19 pandemic including its variants, the Russia-Ukraine conflict and resulting macroeconomic conditions, such as inflation and rising interest rates, and related responses of business and governments to the pandemic and international conflict on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. These statements are not facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our 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 our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 1, 2023. In particular, the extent of COVID 19 including its variants, the Russia-Ukraine conflict and resulting macroeconomic conditions, such as inflation and rising interest rates, impacts on our business will depend on several factors, including the actions taken by governments, businesses, and consumers in response, which continues to evolve and remain uncertain at this time. You can locate these reports through our 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 our expectations to change.

Contact Information:

Amphastar Pharmaceuticals, Inc.
Bill Peters
Chief Financial Officer
(909) 980-9484

SOURCE: Amphastar Pharmaceuticals, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/742570/Amphastar-Pharmaceuticals-Receives-FDA-Approval-for-Naloxone-Hydrochloride-Nasal-Spray-4mg>