

Amphastar Pharmaceuticals Receives FDA Approval for Epinephrine Pre-Filled Syringes

August 16, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / August 16, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration ("FDA") has approved the Company's New Drug Application ("NDA") for Epinephrine injection USP, 1 mg/10mL (0.1 mg/mL) Single Dose Pre-Filled Syringe. Epinephrine injection is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock. For the past 30 years, the Company has sold and marketed Epinephrine injection under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. Net revenues for the Company's Epinephrine injection for the year ended December 31, 2021, were \$27.8 million. Epinephrine injection is the final product that we market under the grandfather exception.

Amphastar's CEO and President, Dr. Jack Zhang, commented: "When we went public eight years ago, we had six products which were marketed under the grandfather exception. The approval of epinephrine pre-filled syringes marks the final approval for these products as ANDAs or NDAs, so we have achieved our commitment to the FDA that we would get approvals for all of these grandfathered products."

Pipeline Information

The Company currently has three ANDAs on file with the FDA targeting products with a market size of approximately \$3.3 billion, three biosimilar products in development targeting products with a market size of approximately \$12 billion, and eight generic products in development targeting products with a market size of approximately \$9 billion. This market information is based on IQVIA data for the 12 months ended June 30, 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 and in the conference call 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, backlog, sales and

marketing of our 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 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 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, 2021, filed with the SEC on March 11, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 2022. 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 including its variants, 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 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.

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