Amphastar Receives FDA Tentative Approval for Vasopressin

December 29, 2021

RANCHO CUCAMONGA, CA / ACCESSWIRE / December 29, 2021 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration ("FDA") has tentatively approved the Company's Abbreviated New Drug Application ("ANDA") for Vasopressin injection, USP 20 Units/mL, 1mL Single Dose Vial. Vasopressin is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. The FDA determined that Amphastar's vasopressin is bioequivalent and therapeutically equivalent to Par Sterile Products LLC's VASOSTRICT® (Vasopressin Injection, USP).

Amphastar's CEO and President, Dr. Jack Zhang, commented: "The FDA's approval of our Vasopressin injection shows the Company's continued commitment and the ability to develop peptide and protein products and the ability to manufacture high-quality injection products for hospital care. The Company will manufacture its Active Pharmaceutical Ingredient (API) and the finished product for Vasopressin in the United States."

According to IQVIA, the U.S. sales for Par's VASOSTRICT® (Vasopressin Injection, USP) 20 Units/mL, 1mL, were approximately $856 million for the 12 months ended September 30, 2021.

The timing of Amphastar's commercialization of its vasopressin product is subject to the confidential terms in the Settlement Agreement between the Company and Par and the FDA's grant of the Final Approval for the ANDA.

Pipeline Information

The Company currently has four ANDAs on file with the FDA targeting products with a market size of approximately $1.8 billion, three biosimilar products in development targeting products with a market size of approximately $13 billion, and eight generic products in development targeting products with a market size of approximately $14 billion. This market information is based on IQVIA data for the 12 months ended September 30, 2021. 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 that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance, 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, the impact of the restructuring of ANP, and other future events, such as the impact of the COVID-19 pandemic including its variants 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, 2020, filed with the SEC on March 15, 2021 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 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 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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