Amphastar Receives FDA Approval for Regadenoson

May 24, 2022

RANCHO CUCAMONGA, CA / ACCESSWIRE / May 24, 2022 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) announced that the U.S. Food and Drug Administration ("FDA") has approved the Company's Abbreviated New Drug Application ("ANDA") for Regadenoson injection, 0.08 mg/mL, 5mL Single Dose Pre-Filled Syringe. Regadenoson is indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. The FDA determined that Amphastar's regadenoson is bioequivalent and therapeutically equivalent to Astellas Pharma U.S., Inc's Lexiscan® (Regadenoson Injection).

Amphastar's CEO and President, Dr. Jack Zhang, commented: "We are excited with the FDA's approval of our Regadenoson injection as this broadens our portfolio of products, highlighting our capabilities in combination product development, while providing patients and healthcare providers with another important option. Both the finished product and Active Pharmaceutical Ingredient (API) will be manufactured in the United States."

According to IQVIA, the U.S. sales for Astellas' Lexiscan® (Regadenoson Injection) were approximately $650 million for the 12 months that ended March 31, 2022.

The timing of commercialization of Amphastar's regadenoson product is subject to the confidential settlement terms agreed to between the Company, and Astellas US LLC.

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 $13 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 March 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.

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 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, 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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