Amphastar Announces Approval for Glucagon for Injection Kit, 1mg

December 29, 2020

RANCHO CUCAMONGA, Calif., Dec. 29, 2020 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ: AMPH) announced that the U.S. Food and Drug Administration (“FDA”) has approved its Abbreviated New Drug Application (“ANDA”) for Glucagon for Injection Emergency Kit, 1 mg. Glucagon is indicated for the treatment of severe hypoglycemia and is also used as a diagnostic aid. Amphastar’s newly approved synthetic peptide product was determined by the FDA to be bioequivalent and therapeutically equivalent to Eli Lilly’s Glucagon Emergency Kit for Low Blood Sugar, which has a recombinant DNA (rDNA)-origin.

Amphastar's CEO and President, Dr. Jack Zhang, commented: "This approval is yet another milestone for the Company and marks the first-ever FDA approval of a generic version of rDNA Glucagon. Using a dedicated process and sophisticated characterization technology, we demonstrated to the Agency that our highly purified synthetic peptide product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), which is an rDNA product. This further highlights Amphastar’s considerable abilities to bring complex generic drugs to the market, and more specifically, our strong peptide capabilities."

According to IQVIA, the U.S. sales for Eli Lilly’s Glucagon Emergency Kit for Low Blood Sugar, 1 mg, were approximately $144 million, and the overall U.S. sales of brand products containing glucagon for injection, 1 mg, were approximately $306 million for the 12 months ended September 30, 2020.

Amphastar plans to launch this Glucagon for Injection Emergency Kit, which it previously referred to as AMP-001, within two months.

Pipeline Information

The Company currently has four ANDAs filed with the FDA, which are targeting products with a market size of approximately $1.4 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 September 30, 2020. The Company is developing multiple proprietary pipeline products for injectable and intranasal dosage forms, including a new drug application for intranasal naloxone and intranasal epinephrine.

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.

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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. 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.

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