

Amphastar Announces Approval for Medroxyprogesterone Acetate Injectable Suspension, USP

November 29, 2017

RANCHO CUCAMONGA, Calif., Nov. 29, 2017 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ:AMPH) announced that today the U.S. Food and Drug Administration ("FDA") granted approval of two abbreviated new drug applications (ANDAs) for Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/mL, 1mL vial, and 1mL prefilled syringe, respectively, indicated for the prevention of pregnancy. Amphastar's newly approved products were determined by the FDA to be therapeutically equivalent to Depo-Provera[®] Contraceptive Injection sold in the United States by Pfizer.

Amphastar's CEO, Dr. Jack Zhang, stated: "We are excited about the approval of Medroxyprogesterone Acetate, which further expands the product offerings in our generic injectable portfolio and highlights our commitment and capability of bringing complex generic drugs to the market."

According to IMS Health (NSP), U.S. brand and authorized generic sales of Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/mL, 1mL vials, and 1mL prefilled syringes were approximately \$316 million for the 12 months ended September 30, 2017.

Amphastar anticipates launching its product in the first quarter of 2018.

Pipeline Information

The Company currently has four abbreviated new drug applications, or ANDAs filed with the FDA, targeting products with a market size of over \$0.5 billion, three biosimilar products in development targeting products with a market size of \$15.0 billion, and 11 generic products in development targeting products with a market size of over \$12.0 billion. This market information is based on IMS Health data for the 12 months ended September 30, 2017. The Company's proprietary pipeline includes NDAs for Primatene[®] Mist and intranasal naloxone. The Company is currently developing several other proprietary products with various dosage forms.

Company Information

Amphastar is a specialty pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable and inhalation 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 is available at the Company's website 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 the Company's expectations regarding litigation matters,

collection of the bond posted by the Plaintiffs and other matters related to its current products, pipeline of product candidates and other future events. These statements are not historical facts but rather are based on Amphastar's current expectations, estimates, and projections regarding Amphastar's business, operations, and other similar or related factors. Words such as "may," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expects," "intends," "plans," "projects," "believes," "estimates," 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. 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.

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