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Amphastar Pharmaceuticals Receives Complete Response Letter for Primatene[®] Mist

RANCHO CUCAMONGA, Calif., Dec. 27, 2016 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ:AMPH) announced today that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to its wholly-owned subsidiary, Armstrong Pharmaceuticals, Inc., for its New Drug Application for Primatene[®] Mist (epinephrine inhalation aerosol).

A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. The CRL indicated that Armstrong should make further changes to the label and packaging for Primatene[®] Mist and then conduct another Human Factor validation study to assess consumers' ability to use the product without the guidance of a doctor or pharmacist. Amphastar is evaluating the content of the letter and plans further discussions with the FDA.

Amphastar's CEO, Dr. Jack Zhang, stated: "While we are disappointed to have not received approval at this time, we intend to continue to work with the FDA during the post-action phase to address their concerns in the CRL by the middle of 2017 and bring Primatene[®] Mist back to the OTC market as soon as possible."

The new Primatene[®] Mist is made with the same active ingredient, epinephrine, that was used in the original Primatene[®] Mist. However, the product's new inhalation delivery system no longer includes chlorofluorocarbons (CFCs), which were phased out of various products worldwide as part of an international environmental treaty. Primatene[®] Mist also includes other important new features, including a built-in spray indicator and a pressurized metal canister that replaces the glass container used in the original Primatene[®] Mist product.

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, Amphastar sells insulin active pharmaceutical ingredient products. Most of Amphastar'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 Amphastar's website at www.amphastar.com.

The Amphastar Pharmaceuticals logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene[®], Amphadase[®] and Cortrosyn[®], are the property of Amphastar Pharmaceuticals, Inc.

Forward Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to Amphastar's expectations regarding sales and marketing of its products, the intended benefits of using its products, the timing of product availability, expectations regarding the timing for seeking FDA approval of its product candidates, and other matters related to its 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. 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 the Company's expectation to change.

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