Amphastar Pharmaceuticals Receives Approval for AMPHADASE(R) Supplement, Marking the First Product From Its China Facility

June 22, 2015

RANCHO CUCAMONGA, Calif., June 22, 2015 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc. (Nasdaq:AMPH) ("Amphastar" or the "Company") announced today that the U.S. Food and Drug Administration ("FDA") granted approval of the Company's New Drug Application ("NDA") supplement for Amphadase® (hyaluronidase injection). This marks the first FDA approved starting material from the Company's subsidiary, ANP, located in Nanjing, China, and signifies that this facility has been qualified by the FDA.

Amphadase® will compete in the hyaluronidase market, which had sales of $23 million for the 12 months ended March 31, 2015, according to IMS Health sales data. The product is used to improve the resorption of radiopaque agents. Amphastar plans to re-launch Amphadase® in the fourth quarter of 2015.

Amphastar's CEO, Dr. Jack Zhang, Ph.D. stated, "We are very happy to have received approval of Amphadase®. In addition to its monetary value, this approval further strengthens our vertical integration strategy, given that ANP will provide the key APIs and starting materials for our pipeline."

The Company currently has three abbreviated new drug applications, or ANDAs, filed with the FDA targeting products with a market size of over $0.5 billion, and another ten generic products in development targeting products with a market size of over $15.0 billion. This market information is based on IMS Health sales data for the 12 months ended March 31, 2015. The Company's proprietary pipeline includes a new drug application, or NDA, for Primatene®. The Company is currently developing six other proprietary drugs, including injectables, inhalation products, nasal sprays, and other 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, in 2014, the Company commenced sales of insulin active pharmaceutical ingredient 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 sales and marketing of its products, the timing of FDA filings 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. 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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