

# Amphastar Pharmaceuticals Receives FDA Approval for Enoxaparin Sodium Injection 300mg/3mL (100mg/mL) Multiple Dose Vial

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RANCHO CUCAMONGA, Calif., March 19, 2019 (GLOBE NEWSWIRE) -- Amphastar Pharmaceuticals, Inc., (NASDAQ: AMPH) announced that the U.S. Food and Drug Administration (FDA) granted approval of its Abbreviated New Drug Application (“ANDA”) for Enoxaparin Sodium Injection 300mg/3mL (100mg/mL) Multiple Dose Vial (MDV). The company currently manufactures and distributes Enoxaparin Sodium Injection in prefilled syringe form and this approval of the Multiple Dose Vial allows the company to begin offering the full line of Enoxaparin products. Amphastar’s newly approved product was determined by the FDA to be therapeutically equivalent to Lovenox<sup>®</sup> (Enoxaparin Sodium Injection) MDV sold in the United States by Sanofi-Aventis. Amphastar plans to launch Enoxaparin MDV in the second quarter of 2019.

According to IQVIA, U.S market annual sales for the 12 months ended December 31, 2018 for Enoxaparin Sodium Injection 300mg/3mL (100mg/mL) MDV was approximately \$11 million.

## Pipeline Information

The Company currently has four abbreviated new drug applications (“ANDAs”) filed with the FDA, which are targeting products with a market size of over \$750 million, three biosimilar products in development targeting products with a market size of approximately \$14.0 billion, and 11 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 December 31, 2018. The Company’s proprietary pipeline includes an NDA for intranasal naloxone. The Company is currently developing four other proprietary products, which include injectable, inhalation and intranasal dosage forms.

## Company Information

Amphastar is a specialty pharmaceutical company that focuses on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable, inhalation and intra-nasal 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](http://www.amphastar.com).

Amphastar’s logo and other trademarks or service marks of Amphastar Pharmaceuticals, Inc., including, but not limited to Primatene<sup>®</sup>, Amphadase<sup>®</sup> and Cortrosyn<sup>®</sup>, 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 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 DMFs, the timing of product launches and the timing of products becoming available on the market, acquisitions 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 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," "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](http://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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