International Medication Systems, Ltd. Receives FDA's Drug Shortage Assistance Award

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Recognized for contributions to address shortage of epinephrine injection, 0.1 mg/mL syringes

RANCHO CUCAMONGA, CA / ACCESS Newswire / March 28, 2025 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) today announced that International Medication Systems, Ltd. ("IMS"), a subsidiary of Amphastar Pharmaceuticals, Inc. ("Amphastar") received a Drug Shortage Assistance Award from the U.S. Food and Drug Administration ("FDA"). This prestigious award recognizes IMS significant efforts in preventing and alleviating critical drug shortages, ensuring that patients have access to essential medications.

IMS is being recognized for its efforts to mitigate and resolve the long-standing drug shortage of epinephrine injection, 0.1 mg/mL syringes, including submitting and obtaining approval of a new drug application for epinephrine injection.

The FDA Drug Shortage Assistance Award honors companies that show a strong commitment to public health and quality manufacturing by taking proactive measures to address drug supply challenges.

"We are deeply honored to receive this recognition from the FDA," said Dr. Jack Zhang, Amphastar's President and Chief Executive Officer. "Our team is dedicated to ensuring a reliable supply of critical medications, and this award validates our ongoing efforts to prioritize patient needs. We understand the importance of consistent access to medicine, and we will continue to work diligently to prevent shortages."

Drug shortages pose a substantial public health threat, delaying and in some cases even denying, critically needed care for patients. Working with drug manufacturers, the FDA helped prevent 145 drug shortages in CY 2017, 160 shortages in CY 2018, 154 in CY 2019, 199 in CY 2020, and 317 in CY 2021, 222 in CY 2022, and 236 in CY 2023.

Amphastar and its subsidiaries are committed to working closely with the FDA and other stakeholders to tackle drug supply issues and ensure that essential medications are available to patients across the country.

Pipeline Information

The Company currently has four abbreviated new drug applications ("ANDAs") on file with the FDA targeting products with a market size exceeding $2 billion, along with four biosimilar products in development targeting products with a market size exceeding $7 billion, and two generic products in development targeting products with a market size of over $1.3 billion. This market information is based on IQVIA data for the 12 months ended December 31, 2024. The Company is developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Co., Ltd. ("ANP"), currently has multiple Drug Master Files ("DMFs"), on file with the FDA and is developing several additional DMFs.

Company Information

Amphastar is a bio-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.

Forward-Looking Statements

All statements in this press release and in the conference call referenced above that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, our future growth, sales and marketing of our products, market size and expansion, product portfolio, product development, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to our pipeline of product candidates, the timing and results of clinical trials, the benefits BAQSIMI®, including its potential for continued revenue growth, the strategic trajectory of and market for our product pipeline, our ability to leverage our existing expertise and technology, and other future events. These statements are not facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our 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, 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, including in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025 and our other filings or reports that we may file with the SEC. In particular, there can be no guarantee that our sales strategies will be successful, or that we will continue to experience significant sales of BAQSIMI®. You can locate these reports through our website at http://ir.amphastar.com and on the SEC's website at www.sec.gov. The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information or any forward-looking statements in this press release or the conference call referenced above to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause our expectations to change.

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