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FDA Approval of Heparin Sodium Injection Continues to Demonstrate Mylan's Deep Expertise in Developing Complex Products

HERTFORDSHIRE, England and PITTSBURGH, Dec. 1, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), a global pharmaceutical company, today announced it has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Applications (ANDAs) for Heparin Sodium Injection USP, 1,000 USP/mL, 5,000 USP/mL, 10,000 USP/mL, and 20,000 USP/mL, all of which are packaged in multi-dose vials.

Heparin is a complex injectable used as an anticoagulant in blood transfusions, extracorporeal circulation and dialysis procedures to prevent and treat various types of blood clots and to treat atrial fibrillation with embolization.

Mylan's President Rajiv Malik commented, "We are very proud of today's FDA approval of Heparin Sodium Injection as this approval adds yet another highly complex and difficult-to-manufacture product to our portfolio. Our investments over the last decade in our scientific and manufacturing capabilities, particularly in the injectables space, continue to pay off as we create a leading portfolio and a robust pipeline of complex products that differentiate us amongst our peers.

"We look forward to adding this product as well as other future product approvals to Mylan's already very robust injectable portfolio, which is one of the largest in the industry, with approximately 80 products available to patients in the U.S. across a broad array of therapeutic categories. We expect to make our Heparin products available to U.S. hospitals in the coming weeks, further supporting our institutional customers in meeting the needs of their patients who depend on high-quality anticoagulants."

U.S. sales for Heparin Sodium Injection USP, 1,000 USP/mL, 5,000 USP/mL, 10,000 USP/mL, and 20,000 USP/mL were approximately $185 million for the 12 months ending Oct. 31, 2017, according to IQVIA.

Currently, Mylan has 211 ANDAs pending FDA approval, representing approximately $93.2 billion in annual brand sales. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing $42.1 billion in annual brand sales, for the 12 months ending August 31, 2017, according to IQVIA. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

This press release includes statements that constitute "forward-looking statements," including with regard to FDA approval of Heparin Sodium Injection demonstrating Mylan's deep expertise in developing complex products; this approval adding yet another highly complex and difficult-to-manufacture product to our portfolio; Mylan's investments over the last decade in our scientific and manufacturing capabilities, particularly in the injectables space, continuing to pay off as Mylan creates a leading portfolio and a robust pipeline of complex products that differentiates us amongst our peers; looking forward to adding this product as well as other future product approvals to Mylan's already very robust injectable portfolio; and expecting to make our Heparin products available to U.S. hospitals in the coming weeks, further supporting our institutional customers in meeting the needs of their patients who depend on high-quality anticoagulants. These statements are made

pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

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