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Mylan Launches First AP-rated Generic Avelox® Injection

HERTFORDSHIRE, England and PITTSBURGH, Oct. 5, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Moxifloxacin Hydrochloride in 0.8% Sodium Chloride Injection, 400 mg/250 mL (1.6 mg/mL) in 250 mL single-dose flexible bags, the first AP-rated generic version of Bayer's Avelox®. The product is being marketed and distributed by Mylan's subsidiary, Mylan Institutional, under a final approval from the U.S. Food and Drug Administration (FDA) for an Abbreviated New Drug Application (ANDA) for this product, which is a fluoroquinolone antibacterial indicated for treating infections in adults caused by designated susceptible bacteria in community acquired pneumonia, skin and skin structure infections, complicated intra-abdominal infections, plague, acute bacterial sinusitis and acute bacterial exacerbation of chronic bronchitis. (1)

Currently, Mylan has 225 ANDAs pending FDA approval, representing approximately $92.5 billion in annual brand sales. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing $41.9 billion in annual brand sales, for the 12 months ending July 31, 2017, according to QuintilesIMS. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

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 approximately 50% of people being treated for HIV/AIDS in the developing world 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.

(1) Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including: tendinitis and tendon rupture, peripheral neuropathy and central nervous system effects. Discontinue this product immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions. Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid this product in patients with known history of myasthenia gravis. Because fluoroquinolones have been associated with serious adverse reactions, reserve this product for use in patients who have no alternative treatment options for the following indications: acute bacterial sinusitis and acute bacterial exacerbation of chronic bronchitis.

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