Mylan Adds First Generic for Canasa® Rectal Suppository to Growing Gastroenterology Portfolio

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Mylan's Mesalamine Rectal Suppository treats mildly to moderately active ulcerative proctitis
The company is awarded 180 days of marketing exclusivity

HERTFORDSHIRE, England and PITTSBURGH, Dec. 17, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced the U.S. launch of Mesalamine Rectal Suppository, 1000 mg, the first generic version of Allergan's Canasa® Rectal Suppository, 1000 mg. Mylan Pharmaceuticals received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is for the treatment of mildly to moderately active ulcerative proctitis. According to the FDA approval letter, Mylan was the first applicant to submit a substantially complete ANDA for Mesalamine Rectal Suppository, 1000 mg, containing a Paragraph IV certification, and is eligible for 180 days of generic drug exclusivity.

U.S. sales for Mesalamine Rectal Suppository, 1000 mg, were approximately $263 million for the 12 months ending October 31, 2018, according to IQVIA.

Currently, Mylan has 168 ANDAs pending FDA approval representing approximately $85.5 billion in annual brand sales, according to IQVIA. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing $50.4 billion in annual brand sales, for the 12 months ending June 30, 2018, according to IQVIA.

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 approximately 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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