



Launch of Generic Lialda® Delayed-Release Tablets Expands Mylan's Gastroenterology Product Offering

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Mesalamine Delayed-Release Tablets help individuals manage their ulcerative colitis.

HERTFORDSHIRE, England and PITTSBURGH, Dec. 17, 2018 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) today announced the U.S. launch of Mesalamine Delayed-Release Tablets USP, 1.2 g, a generic version of Shire's Lialda® Delayed-Release Tablets. 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 indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis (UC) and for the maintenance of remission of UC.

U.S. sales for Mesalamine Delayed-Release Tablets USP, 1.2 g, were approximately \$842 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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SOURCE Mylan N.V.

Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813