Mylan Launches Generic Suboxone® Sublingual Film to Treat Opioid Dependence

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HERTFORDSHIRE, England and PITTSBURGH, Feb. 22, 2019 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced the U.S. launch of Buprenorphine and Naloxone Sublingual Film, 8 mg/2 mg and 12 mg/3 mg, a generic version of Indivior's Suboxone® Sublingual Film. 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 treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

Prescription of this product is limited to healthcare providers who meet certain qualifying requirements including notification to Department of Health and Human services of their intent to prescribe this product.

U.S. sales for Buprenorphine and Naloxone Sublingual Film, 8 mg/2 mg and 12 mg/3 mg, were approximately $1.87 billion for the 12 months ending December 31, 2018, according to IQVIA.

Currently, Mylan has 173 ANDAs pending FDA approval representing approximately $85.8 billion in annual brand sales, according to IQVIA. Forty-six of these pending ANDAs are potential first-to-file opportunities, representing $53.6 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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