



## Mylan Adds to Growing Oncology Portfolio with Launch of Generic Mutamycin® Injection

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### - Mitomycin for Injection is available to Mylan's hospital and other institutional customers -

HERTFORDSHIRE, England and PITTSBURGH, March 20, 2018 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ:MYL) today announced the U.S. launch of the oncology drug Mitomycin for Injection USP, 5 mg/vial, 20 mg/vial and 40 mg/vial Single Dose Vials, a generic version of the reference listed drug, Bristol Myers Squibb's Mutamycin®. The product is used in combination with other cancer medicines in the treatment of stomach and pancreatic cancers.

Mylan is offering Mitomycin for Injection USP, 5 mg/vial, 20 mg/vial and 40 mg/vial Single Dose Vials to its hospital and institutional customers after an Abbreviated New Drug Application (ANDA) for the product was approved by the U.S. Food and Drug Administration (FDA).

Mylan's injectables portfolio is one of the largest and most diversified in the industry, with approximately 80 injectable products in the U.S. across several therapeutic areas. Mylan is also one of the largest suppliers of cancer medicines by volume in the U.S.

U.S. sales for Mitomycin for Injection USP, 5 mg/vial, 20 mg/vial and 40 mg/vial Single Dose Vials were approximately \$59 million for the 12 months ending Jan. 31, 2018, according to IQVIA.

Currently, Mylan has 206 ANDAs pending FDA approval representing approximately \$93.8 billion in annual brand sales, according to IQVIA. Forty-six of these pending ANDAs are potential first-to-file opportunities, representing \$42.2 billion in annual brand sales, for the 12 months ending December 31, 2017, according to IQVIA.

According to its indication, Mitomycin Injection is not recommended as a single-agent, primary therapy. It has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Mitomycin is not recommended to replace appropriate surgery and/or radiotherapy. (1)

(1) Mitomycin should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of mitomycin.

Hemolytic Uremic Syndrome (HUS) a serious complication of chemotherapy, consisting primarily of macroangiopathic hemolytic anemia, thrombocytopenia, and irreversible renal failure, has been reported in patients receiving systemic mitomycin. The syndrome may occur at any time during systemic therapy with mitomycin as a single agent or in combination with other cytotoxic drugs; however, most cases occur at doses  $\geq 60$  mg of mitomycin. Blood product transfusion may exacerbate the symptoms associated with this syndrome. The incidence of the syndrome has not been defined.

#### 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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