



Mylan Launches Generic Angiomax® Injection

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- Bivalirudin for Injection is an anticoagulant intended for use with aspirin -

HERTFORDSHIRE, England and PITTSBURGH, June 18, 2018 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) today announced the U.S. launch of Bivalirudin for Injection, 250 mg single-dose vial, a generic version of Angiomax® from The Medicines Company. The product is a direct thrombin inhibitor indicated for use as an anticoagulant in patients.

Mylan is offering Bivalirudin for Injection, 250 mg single-dose vial, 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).

Bivalirudin for Injection is indicated for use as an anticoagulant in patients:

- with unstable angina undergoing percutaneous transluminal coronary angioplasty;
- undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) as in the REPLACE-2 study;
- or with, or at risk of, heparin-induced thrombocytopenia (HIT) or heparin induced thrombocytopenia and thrombosis syndrome (HITTS), undergoing PCI.

It is intended for use in these indications with aspirin. The safety and effectiveness have not been established in patients with acute coronary syndromes who are not undergoing PTCA or PCI.

Bivalirudin for Injection, 250 mg single-dose vial, had U.S. sales of approximately \$106 million for the 12 months ending March 31, 2018, according to IQVIA.

Currently, Mylan has 199 ANDAs pending FDA approval representing approximately \$88.5 billion in annual brand sales, according to IQVIA. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$45.5 billion in annual brand sales, for the 12 months ending December 31, 2017, 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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Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813