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Hospira announces the US launch of generic Bivalirudin

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Hospira has announced that it has obtained the US Food and Drug Administration (US FDA) approval for the launch of bivalirudin for injection, a generic version of The Medicines Company's Angiomax. Branded sales of Angiomax in 2014 in the United States were approximately $500 million.

Hospira's bivalirudin for injection is available in a single-dose flip-top vial, which matches the current branded offering available. In addition, the company plans to launch a differentiated presentation of the 250 mg bivalirudin for injection in its unique ADD-Vantage vial.

"Hospira is excited to launch the first generic of bivalirudin based on a successful challenge of the originator's patents. This approval further demonstrates our commitment to bringing safe, lower-cost generic versions of important medications to the market as soon as possible," said Mr Philippe Drouet, president, the US Commercial, Hospira.

Available as a lyophilized (powder) format, Hospira's bivalirudin for injection is a direct thrombin inhibitor indicated for use as an anticoagulant in patients With unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA); Undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) as in the REPLACE-2 study, and With, or at risk of, heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis syndrome (HITTS), undergoing PCI.

Bivalirudin is intended for use with aspirin.