Endo Launches Bivalirudin Injection in Ready-to-Use Vials

July 18, 2023

- *Only ready-to-use liquid format of bivalirudin on the market*
- *Does not require reconstitution, dilution or mixing, which helps increase efficiency for hospitals and healthcare providers*

DUBLIN, July 18, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that its Par Sterile Products business has begun shipping bivalirudin injection in a ready-to-use 250 mg/50 mL single-use vial. It is the only ready-to-use liquid format of bivalirudin on the market in the U.S.

"Hospital practitioners work hard to provide quality patient care while also meeting operational challenges," said Scott Sims, Senior Vice President and General Manager, Injectable Solutions & Generics at Endo. "With ready-to-use products like bivalirudin, we're helping to deliver solutions that reduce complexity for healthcare providers—so they can focus on patient care."

In May 2023, Endo executed agreements with MAIA Pharmaceuticals, Inc. and Gland Pharma Limited, India to commercialize ready-to-use bivalirudin in the U.S. The product, manufactured by Gland Pharma Limited, is an anticoagulant (thrombin inhibitor) that helps prevent the formation of blood clots. It is used to prevent blood clots in people with severe chest pain or other conditions who are undergoing an angioplasty procedure.

Ready-to-use, or RTU, products streamline operations for hospitals by eliminating the need to prepare or transfer the product before patient administration. This may reduce waste and costs, optimize convenience and workflow and reduce the chance for preparation error—all of which support quality patient care.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Bivalirudin injection is contraindicated in patients with:

- Significant active bleeding;
- Hypersensitivity to bivalirudin injection or its components

WARNINGS AND PRECAUTIONS
Bleeding Events
Bivalirudin increases the risk of bleeding. Bivalirudin's anticoagulant effect subsides approximately one hour after discontinuation.
Thrombotic Risk with Coronary Artery Brachytherapy
An increased risk of thrombus formation, including fatal outcomes, has been associated with the use of bivalirudin in gamma brachytherapy.

ADVERSE REACTIONS
The most common adverse reaction was bleeding (3.7%).

DRUG INTERACTIONS
In clinical trials in patients undergoing percutaneous coronary intervention (PCI), co-administration of bivalirudin with heparin, warfarin, thrombolytics, or GPIs was associated with increased risks of major bleeding events compared to patients not receiving these concomitant medications.

USE IN SPECIFIC POPULATIONS
Geriatric Use
In studies of patients undergoing PCI, 44% were ≥65 years of age and 12% of patients were ≥75 years old. Elderly patients experienced more bleeding events than younger patients.
Renal Impairment

The disposition of bivalirudin was studied in PTCA patients with mild, moderate and severe renal impairment. The clearance of bivalirudin was reduced approximately 21% in patients with moderate and severe renal impairment and was reduced approximately 70% in dialysis- dependent patients. The infusion dose of bivalirudin injection may need to be reduced, and anticoagulant status monitored in patients with renal impairment.

INDICATION AND USAGE
Bivalirudin injection is indicated for use as an anticoagulant in patients undergoing PCI, including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome.

Please click for Full Prescribing Information.

About Endo
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Mr. Sims, any statements relating to product launch, efficiencies, commercialization, competition or sales, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

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