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**Media Contact**
Eric Tatro, (224) 948-5353
media@baxter.com

**Investor Contact**
Clare Trachtman, (224) 948-3085

# BAXTER ANNOUNCES U.S. FDA APPROVAL OF READY-TO-USE CARDIOVASCULAR MEDICATION BIVALIRUDIN

- *First presentation of bivalirudin in frozen, premixed, ready-to-use formulation*

**DEERFIELD, Ill., January 22, 2018** – Baxter International Inc. (NYSE: BAX), a global leader in sterile medication production and delivery, today announced the U.S. Food and Drug Administration (FDA) approval of Bivalirudin in 0.9 percent Sodium Chloride Injection (bivalirudin). Bivalirudin is a specific and direct thrombin inhibitor indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), a common non-surgical procedure to treat blocked or narrowed blood vessels in the heart.

"The approval of bivalirudin demonstrates how Baxter brings its innovative technologies together with medicines in ways that help promote efficiency for clinicians," said Robert Felicelli, president, Pharmaceuticals, Baxter. "Baxter's presentation of this widely used cardiovascular medication is the first and only available in a convenient frozen premixed solution."

Bivalirudin will use Baxter's proprietary frozen GALAXY container technology, a non-PVC and non-DEHP system specifically designed to create a ready-to-use format for unstable molecules. Premixed versions of commonly prescribed drugs help simplify

the preparation process and can avoid potential errors that may occur when medications are compounded. Compounding is the process of combining different ingredients in specific quantities to fill individualized prescriptions.

Baxter's premixed medications are manufactured to current Good Manufacturing Practice (cGMP) regulations established and monitored by the FDA. Bivalirudin is expected to launch in the United States in early 2018 in two commonly prescribed dosage forms and strengths: 250 mg of bivalirudin per 50 mL (5 mg/mL) and 500 mg of bivalirudin per 100 mL (5 mg/mL).

**About Baxter Pharmaceuticals**

Baxter provides a wide range of high-value generic injectable medicines that help treat some of the most pressing healthcare needs facing patients today, including difficult-to-manufacture oncology drugs and standard-dose, ready-to-use premixed injectable anti-infectives, analgesics and critical care medicines. Baxter has rapidly expanded its pharmaceuticals portfolio through recent acquisitions, strategic partnerships and internal development programs that will help increase access to essential medicines and advance pharmacy efficiency and patient care. Baxter is also the first and only company to offer all three of the most commonly used modern inhaled anesthetics for general anesthesia.

**About Baxter**

Baxter provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and

devices; parenteral nutrition; surgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

**Indications and Usage for BIVALIRUDIN in 0.9% Sodium Chloride Injection, for intravenous use**

Bivalirudin Injection is a direct thrombin inhibitor indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI).

**Important Risk Information for BIVALIRUDIN in 0.9% Sodium Chloride Injection, for intravenous use**

- Bivalirudin is contraindicated in patients with significant active bleeding or hypersensitivity to bivalirudin injection or its components.
- Bivalirudin increases the risk of bleeding. Its anticoagulant effect subsides approximately one hour after discontinuation.
- Bivalirudin is associated with an increased risk of thrombus formation, including fatal outcomes, in gamma brachytherapy.
- In the original bivalirudin clinical trials the most common adverse reaction was bleeding.
- Bivalirudin is associated with increased major bleeding risk with concomitant use of heparin, warfarin, thrombolytics or GPIs.
- In geriatric populations, increased bleeding risk is possible.
- In patients with renal impairment, reduce infusion dose and monitor ACT.

Please see accompanying full Prescribing Information.

*This release includes forward-looking statements concerning bivalirudin, including expectations with regard to its anticipated availability in the U.S. and anticipated benefits associated with its use. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and*

*regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*



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