



## GLAND PHARMA

# Announces Launch of the First Novel Non-Frozen Ready-To-Use Bivalirudin

---

Hyderabad, India, June 5, 2020

GLAND PHARMA Ltd. (Gland Pharma), along with its partners MAIA Pharmaceuticals, Inc. (MAIA) and Athenex Pharmaceutical Division (APD) announce the launch of a Ready-to-Use (RTU) Bivalirudin Injection in the United States of America. This is the first non-frozen ready-to-use bivalirudin 505b(2) NDA approved by the U.S. Food and Drug Administration (USFDA).

Bivalirudin RTU Injection is indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome.

Bivalirudin RTU Injection is available to order from APD in a 250mg/50mL (5mg/mL concentration) Piggyback Vial.

The product is manufactured by Gland Pharma Ltd. (Gland), a globally renowned manufacturer of Small Volume Parenterals (SVPs) located in India.

“We are pleased to collaborate with MAIA and Athenex in bringing to market the RTU non-Frozen Version of Bivalirudin Injection. We believe that this complements our commitment to provide Easy to Use, Safe to Deliver, Cost Effective Products to clinicians” said Srinivas Sadu, MD and CEO of Gland Pharma Limited.

“We are delighted to introduce a unique RTU Bivalirudin Injection that does not require frozen storage into the US hospital market,” said Jeffrey Yordon, Athenex's Chief Operating Officer. “The launch of this innovative product underlines the unique ability of Athenex to work quickly and collaboratively to bring much needed products to our customers. We'd like to thank our partners at MAIA and Gland for matching our agility, enabling our speed to market, and supporting our unwavering commitment to delivering high-quality products that can help address our customers' ongoing needs.”

Srikanth Sundaram, Ph.D., President of MAIA, added, “We are thrilled with the launch of MAIA's NDA product in partnership with the seasoned and exceptional team at Athenex and Gland. Bivalirudin RTU Injection, which does not need reconstitution and further dilution unlike the lyophilized version, essentially eliminates the drug preparation process. By avoiding potential errors in the drug preparation and administration process and associated adverse events, its use offers benefits to the patient.”

**About Gland Pharma:** Established in Hyderabad, India in 1978, Gland Pharma is one of the fastest growing small molecule generic injectables-focused company, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India and other markets in Rest of the world. Gland Pharma has seven manufacturing facilities in India, comprising four facilities for finished formulations and three API facilities. We are focused on meeting diverse injectables needs with a stable supply of affordable and high quality products. We have established a portfolio of injectables products across various therapeutic segments and delivery systems and are present in sterile injectables, oncology and ophthalmics with focus on complex injectables.

---

Corporate Office: Sy No 143-148, 150 & 151, Gandimaisamma X Roads, DP Pally, Hyderabad - 500043, Telangana, India.

Tel: +91-40-30510999 | Fax: +91-40-3051 0800 | e-mail: gland@glandpharma.com

www.glandpharma.com