



Press Release

For immediate release

CAPLIN STERILES GETS USFDA APPROVAL FOR MILRINONE LACTATE INJECTION

Chennai, April 19, 2021: Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT) Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited, has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Milrinone Lactate Injection USP, 10 mg/10 mL (1 mg/mL), 20 mg/20 mL (1 mg/mL), 50 mg/50 mL (1 mg/mL), Single-dose vial presentation, a generic therapeutic equivalent version of (RLD), PRIMACOR Injection, 1 mg/mL, of Sanofi-Aventis U.S. LLC.

Milrinone lactate injection is indicated for the short-term intravenous treatment of patients with acute decompensated heart failure. According to IQVIA™ (IMS Health), Milrinone Lactate Injection had US sales data of approximately \$24 million for the 12-month period ending Dec 2020, for both the Vial and Bag presentations, the latter of which is under development at Caplin Steriles.

Mr. C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented “We’re expecting approvals for 3 more products this Quarter and we’re working on launches for 9 products in the next few months from the site.”

ABOUT CAPLIN STERILES LTD

Caplin Steriles Ltd, a Subsidiary of Caplin Point Laboratories Limited, is a niche sterile product manufacturing company that is approved by US FDA and EU-GMP. Caplin Steriles Limited has developed and filed 20 ANDAs in USA on its own and with partners, with 13 approvals so far. The Company is also working on a portfolio of around 45 simple and complex Injectable and Ophthalmic products, that it intends to file over the next 4 years.

ABOUT CAPLIN POINT LABORATORIES LIMITED

Caplin Point Laboratories Limited is a fast-growing pharmaceutical Company with a unique business model catering predominantly to emerging markets of Latin America and Africa. Caplin Point has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. The Company’s Subsidiary Caplin Steriles Limited caters to the Regulated Markets for Injectable and Ophthalmic products.



Caplin Point Laboratories Limited has been selected on Forbes Asia's "200 Best Under a Billion" list for three consecutive years (2014, 2015 & 2016), and was awarded "The Emerging Company of 2018" and "Business Excellence Award for 2019" by Economic Times.

Cautionary Statement:

This press release contains certain forward-looking statements. Any forward-looking statement applies only on the date of this press release. By their nature, forward-looking statements are subject to a number of known and unknown risks and uncertainties that may or may not occur in the future and as a result of which the actual results and performance may differ substantially from the expected future results or performance expressed or implied in the forward looking statements. No warranties or representations are made as to the accuracy, achievement or reasonableness of such statements, estimates or projections, and Caplin Point has no obligation to update any such information or to correct any inaccuracies herein or omission here from which may become apparent.

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