



Press Release

For immediate release

CAPLIN STERILES GETS USFDA APPROVAL FOR LABETALOL HYDROCHLORIDE INJECTION USP

Chennai, September 08, 2021: Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT) Caplin Steriles Limited (Caplin), a Subsidiary 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) Labetalol Hydrochloride Injection USP, 100 mg/20 mL (5 mg/mL) and 200 mg/40 mL (5 mg/mL) Multiple-dose Vials, a generic therapeutic equivalent version of (RLD), TRANDATE Injection, of Sebela Ireland Limited.

Labetalol Hydrochloride Injection USP is indicated for control of blood pressure in severe hypertension. According to IQVIA™ (IMS Health), Labetalol hydrochloride Injection had US sales data of approximately \$6 million for the 12-month period ending June 2021.

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, EU-GMP, ANVISA-Brazil and several other regulatory agencies. Caplin Steriles Limited, has developed and filed 20 ANDAs in USA on its own and with partners, with 17 approvals so far. Out of the 17 approvals, 12 belong to Caplin Steriles. The Company is also working on a portfolio of 45 simple and complex Injectable and Ophthalmic products to be filed 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 recently 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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