

Caplin Point Laboratories Limited

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CIN: L24231TN1990PLC019053

March 08, 2023

BSE Limited

Department of Corporate Relationship 1st Floor, New Trade Ring, Rotunda Building Phiroze Jeejeebhoy Towers Dalal Street, Mumbai- 400001 Scrip Code: 524742

National Stock Exchange of India Ltd

Department of Corporate Services Exchange Plaza, 5th Floor, C-1, Block G, Bandra Kurla Complex, Bandra (E), Mumbai - 400 051 Scrip Code: CAPLIPOINT.

Dear Sir/Madam,

Sub: Press Release - Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Attaching herewith a Press Release regarding grant of USFDA approval for Abbreviated New Drug Application (ANDA) Thiamine Hydrochloride Injection USP, to our Subsidiary Caplin Steriles Limited. Request you to take the same on record.

Thanking You,

Sincerely Yours

For Caplin Point Laboratories Limited

VENKATRAM GANAPATHISUBRA GANAPATHISUBRAMANIAN Date: 2023.03.08 10:45:23 **MANIAN**

Digitally signed by VENKATRAM +05'30'

Venkatram G **General Counsel & Company Secretary** Membership No. A23989 Encl: A/a



CAPLIN STERILES GETS USFDA APPROVAL FOR THIAMINE HYDROCHLORIDE INJECTION

Chennai, March 08, 2023: Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT), has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Thiamine Hydrochloride Injection USP, 200 mg/2 mL (100 mg/mL) Multi-dose Vial, a generic therapeutic equivalent version of (RLD), THIAMINE HYDROCHLORIDE injection of Fresenius Kabi USA LLC.

Thiamine Hydrochloride Injection is effective in the treatment of Thiamine (Vitamin B1) deficiency or beriberi, a serious condition caused by prolonged lack of Vitamin B1. According to IQVIATM (IMS Health), Thiamine Hydrochloride Injection had US sales of approximately \$38 million for the 12-month period ending September 2022.

Mr. C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented "We're glad to receive 3 back to back ANDA approvals recently, taking the tally to 16 approvals for Caplin Steriles and 4 more with partners. These recent approvals will not only help the company's current targets, but also the future."

About Caplin Steriles Limited

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a niche sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP and ANVISA. Caplin Steriles Limited, has developed and filed 29 ANDAs in USA on its own and with partners, with 20 approvals so far. The Company is also working on a portfolio of 40+ 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 is one of the few companies to show consistent high-quality growth in Revenues, Profits and Cash flow over the last 15 years. The Company has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. The Company has also entered regulated markets such as US through its Subsidiary Caplin Steriles Limited.

Caplin Point listed on **Forbes "Asia's 200 Best Under a Billion"** list for 2022. Company has appeared fifth time on this list (2014, 2015, 2016, 2021 and 2022) and was awarded "The Emerging Company of 2018" by Economic Times Family Business Awards.

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

Press Release



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.

For details, please contact:

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Ernst & Young

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ISIN: INE475E01026 NSE Code: CAPLIPOINT BSE CODE: 524742

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