

**May 12, 2023**

**BSE Limited**

Department of Corporate Relationship  
1<sup>st</sup> 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, 5<sup>th</sup> 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 United States Food and Drug Administration (USFDA) approval for the Abbreviated New Drug Application (ANDA) Ketorolac Tromethamine 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

GANAPATHISUBR

AMANIAN

Digitally signed by VENKATRAM  
GANAPATHISUBRAMANIAN  
Date: 2023.05.12 11:21:36  
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**Venkatram G**

**General Counsel & Company Secretary**

**Membership No. A23989**

**Encl: A/a**

## **CAPLIN STERILES GETS USFDA APPROVAL FOR KETOROLAC TROMETHAMINE INJECTION**

**Chennai, May 12, 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) Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL Single-dose Vial, a generic therapeutic equivalent version of (RLD), TORADOL injection of Roche.

Ketorolac Tromethamine Injection USP is a nonsteroidal anti-inflammatory drug (NSAID), indicated for the short-term ( $\leq 5$  days) management of moderately severe acute pain. According to IQVIA<sup>™</sup> (IMS Health), Ketorolac Tromethamine Injection USP had US sales of approximately \$53 million for the 12-month period ending December 2022.

**Mr. C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented** “Our regulated markets business continues to grow at a robust pace, and this new approval will help augment the growth. We have also received a few approvals from other markets such as Canada and Australia and we look forward to launches there within this year too.”

### **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 30 ANDAs in USA on its own and with partners, with 21 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, Canada, Australia etc 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 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:**

<p><b>Investor Relations at Caplin</b> Mr G Venkatram (General Counsel &amp; Company Secretary) Tel: +91 44 24968000 <a href="mailto:investor@caplinpoint.net">investor@caplinpoint.net</a></p> <p><b>Ernst &amp; Young</b> Mr. Rahul Thakur <a href="mailto:Rahul.thakur@in.ey.com">Rahul.thakur@in.ey.com</a></p>	<p><b>Registered Office</b> Caplin Point Laboratories Limited 3<sup>rd</sup> Floor, Ashvich Tower, No. 3, Developed Plots Industrial Estate, Perungudi, Chennai – 600 096, Tamil Nadu, INDIA. Tel: +91 44 2496 8000 CIN: L24231TN1990PLC019053 ISIN: INE475E01026 NSE Code: CAPLIPOINT BSE CODE: 524742 Website: <a href="http://www.caplinpoint.net">www.caplinpoint.net</a></p>
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