

22.01.2021

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

By BSE Listing

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.

By NEAPS

Dear Sirs,

SUB:PRESS RELEASE- DISCLOSURE UNDER REGULATION 30 OF SEBI (LISTING OBLIGATIONS AND DISCLOSURE REQUIREMENTS) REGULATIONS,2015

Please find the enclosed copy of Press Release being published today.

Kindly take the same on your records.

Thanking You,

Yours Faithfully,
For Caplin Point Laboratories Limited


Company Secretary
Enclosure: As above



Press Release

For immediate release

CAPLIN STERILES GETS USFDA APPROVAL FOR ARGATROBAN INJECTION

Chennai, January 22, 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) Argatroban Injection, 50 mg/50 mL (1 mg/mL) Single-dose vial presentation, a generic therapeutic equivalent version of (RLD), ARGATROBAN INJECTION, of Hikma Pharmaceuticals Limited.

Caplin has received a CGT (Competitive Generic Therapies) Grant for this ANDA and **Caplin is the “first approved applicant” for such competitive generic therapy**, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, **Caplin is eligible for 180 days of CGT exclusivity for Argatroban Injection, 50 mg/50 mL (1 mg/mL) Single- Dose Vial, under section 505(j)(5)(B)(v) of the FD&C Act.**

Argatroban is used as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia. According to IQVIA™ (IMS Health), Argatroban Injection had US sales data of approximately \$18 million for the 12-month period ending Sep 2020.

Mr. C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented “We’re excited to receive our first approval with CGT exclusivity from our pipeline. We will target launching the product within the shortest time possible.”

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 12 approvals so far. The Company is also working on a portfolio of 35 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 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.

For details, please contact:

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