

22<sup>nd</sup> May 2024

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|---|---|
| <p>(1) BSE Limited<br/>Listing Department,<br/>Phiroze Jeejeebhoy Towers,<br/>Dalal Street,<br/>Mumbai 400 001</p> <p><b>Scrip Code: 500087</b></p> | <p>(2) National Stock Exchange of India Limited<br/>Listing Department<br/>Exchange Plaza, 5<sup>th</sup> floor,<br/>Plot no. C/1, G Block,<br/>Bandra Kurla Complex,<br/>Bandra (East), Mumbai - 400 051</p> <p><b>Scrip Code: CIPLA</b></p> |
| <p>(3) SOCIETE DE LA BOURSE DE LUXEMBOURG<br/>Societe Anonyme<br/>35A Boulevard Joseph II,<br/>L-1840 Luxembourg</p>                                |   |

**Sub: Cipla receives final approval for the generic version of Somatuline® Depot (lanreotide) Injection 120 mg/ 0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL**

Dear Sir/Madam,

In compliance with the provisions of Regulation 30 of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015 read with SEBI circular No. SEBI/HO/CFD/CFD-PoD-1/P/CIR/2023/123 dated 13<sup>th</sup> July, 2023, we are enclosing a disclosure in Annexure-1 and a press release dated 22<sup>nd</sup> May 2024 on the captioned subject.

Kindly take the above information on record.

Thanking you,  
Yours faithfully,  
**For Cipla Limited**

**Rajendra Chopra**  
**Company Secretary**

Prepared by: Mandar Kurghode

**Annexure – I**

Details as per the SEBI circular No. SEBI/HO/CFD/CFD-PoD-1/P/CIR/2023/123 dated 13<sup>th</sup> July, 2023

Sr. No.	Particulars	Details
a)	name of the regulatory or licensing authority;	United States Food and Drugs Administration (USFDA)
b)	brief details of the approval/license obtained/ <del>withdrawn/ surrendered</del>	Cipla USA Inc., wholly owned subsidiary of the Company in USA (hereinafter referred as “Cipla”) has received the final approval for its Abbreviated New Drug Application (ANDA) for Lanreotide Injection 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL from USFDA. Cipla’s Lanreotide Injection is AP-rated therapeutic equivalent generic version of Somatuline® Depot (lanreotide) Injection and is indicated for the treatment of patients with Acromegaly and Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs).
c)	impact/relevance of such approval/license to the listed entity;	The approval for the generic version of Lanreotide Acetate is in line with Cipla’s growth strategy in the complex product segment and will strengthen Cipla's position in the US market.
d)	withdrawal/cancellation or suspension of licence/approval by the regulatory or licensing authority, with reasons for such action, estimated impact (monetary or otherwise) on the listed entity and penalty, if any;	Not applicable
e)	period for which such approval/license is/was valid;	Once approved, ANDA approval remains valid as long as the drug product complies with the USFDA regulations and standards.
f)	Subsequently, the listed entity shall inform the stock exchange(s), the actual impact (monetary or otherwise) along with corrective actions taken by the listed entity pursuant to the withdrawal, cancellation or suspension of the key license/ approval.	Not applicable

Press Release

## **Cipla receives final approval for the generic version of Somatuline® Depot (lanreotide) Injection 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL**

**Mumbai, India & Warren, New Jersey, USA, May 22, 2024:** Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") and its wholly owned subsidiary Cipla USA Inc., (hereafter referred to as "Cipla"), today announced that it has received the final approval for its Abbreviated New Drug Application (ANDA) for Lanreotide Injection 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL from the United States Food and Drug Administration (USFDA).

Cipla's Lanreotide Injection is AP-rated therapeutic equivalent generic version of Somatuline® Depot (lanreotide) Injection. Lanreotide Injection is supplied as 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL single-dose, pre-filled, ready-to-inject syringe. Cipla's Lanreotide injection is indicated for the treatment of patients with Acromegaly and Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs).

According to IQVIA (IMS Health), Somatuline® Depot (Lanreotide) had US sales of approximately \$898M for the 12-month period ending March 2024.

### **About Cipla:**

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective, and CNS segments are well-known. Our 47 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Feb'24), 1st in the pharma prescription market in South Africa (IQVIA MAT Feb'24), and 4th largest by prescription in the US Gx inhalation products (IQVIA MAT Feb'23). For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less

than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility, and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers, and all stakeholders.

For more, please visit <https://www.cipla.com>, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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