



November 1, 2019

✓ **The BSE Limited,**  
Department of Corporate Services,  
P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
**MUMBAI - 400 001.**

**The National Stock Exchange of India Ltd.,**  
Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**MUMBAI - 400 051.**

Dear Sir/Madam,

**Sub: Disclosure pursuant to Regulation 30 of the SEBI**  
**(Listing Obligations and Disclosure Requirements) Regulations, 2015.**

Enclosed is a Press Release as regards receipt of approval from the U.S. FDA for Company's sANDA Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, to market a generic equivalent of LEVOXYL® 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, manufactured by King Pharmaceuticals Research and Development LLC.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Thanking you,

For LUPIN LIMITED

**R. V. SATAM**  
**COMPANY SECRETARY**  
**(ACS - 11973)**



Encl.: a/a

LUPIN LIMITED

Registered Office: 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel : (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

[www.lupin.com](http://www.lupin.com)

## **Lupin receives sANDA approval from US FDA for Levothyroxine Sodium Tablets USP AB rating to Reference Listed Drug, LEVOXYL®**

**Mumbai, Baltimore, November 01, 2019:** Pharma major Lupin Limited (Lupin) announced that it has received approval for its sANDA for Levothyroxine Sodium Tablets USP from the United States Food and Drug Administration (U.S. FDA), to market a generic equivalent of LEVOXYL® 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, manufactured by King Pharmaceuticals Research and Development LLC.

Lupin's Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg was originally approved on January 18, 2019 as generic equivalent of SYNTHROID® manufactured by ABBVIE Inc.

Earlier, Lupin also received sANDA approval dated September 19, 2019 for its Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, from the United States Food and Drug Administration (U.S. FDA), to market a generic equivalent of UNITHROID® manufactured by Jerome Stevens Pharmaceuticals Inc.

With this sANDA approval, Lupin's Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg are now AB rated (therapeutically equivalent) with Reference Listed Drugs, SYNTHROID®, UNITHROID® and LEVOXYL® and are the only product approved with FDA's new Narrow Therapeutic Index guidance for Levothyroxine.

Lupin's Levothyroxine Sodium Tablets are indicated for:

- Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer

Cumulatively, Levothyroxine Sodium Tablets USP (RLDs: SYNTHROID®, UNITHROID® and LEVOXYL®) had annual sales of approximately USD 2,581 million in the US (IQVIA MAT June 2019).

### **About Lupin Limited**

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 8<sup>th</sup> largest generics pharmaceutical company by revenues (31<sup>st</sup> Mar 2019, Bloomberg LTM) respectively. The Company is the 3<sup>rd</sup> largest pharmaceutical player in the US by prescriptions (IQVIA MAT Jun 2019); 3<sup>rd</sup> largest Indian pharmaceutical company by global revenues (31<sup>st</sup> Mar 2019, Bloomberg LTM); 5<sup>th</sup> largest generic pharmaceutical player in Japan and 6<sup>th</sup> largest company in the Indian Pharmaceutical Market (IQVIA MAT Jun 2019).

For the financial year ended 31<sup>st</sup> March 2019, Lupin's Consolidated sales and Net profits were at Rs. 163,694 million (USD 2.34 billion) and Rs. 9,466 million (USD 136 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – [www.twitter.com/lupinglobal](http://www.twitter.com/lupinglobal)

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

**For further information or queries please contact:**

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**\*Safe Harbor Statement**

LEVOXYL® is the registered trademark of King Pharmaceuticals Research and Development LLC.

UNITHROID® is the registered trademark of Jerome Stevens Pharmaceuticals Inc.

SYNTHROID® is the registered trademark of AbbVie Inc.