Press Release

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Lupin receives sANDA approval from U.S. FDA for Levothyroxine Sodium Tablets USP to be considered AB rated to Reference Listed Drug, UNITHROID®

Mumbai, Baltimore, September 20, 2019: Pharma major Lupin Limited (Lupin) announced that it has received approval for its sANDA for 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® 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 Jerome Stevens Pharmaceuticals Inc.

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® 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 ABBVIE 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® and UNITHROID®.

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

Levothyroxine Sodium Tablets USP (RLD: UNITHROID® and SYNTHROID®) had annual sales of approximately USD 2581 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 8th largest generics pharmaceutical company by revenues (31st Mar 2019, Bloomberg LTM) respectively. The Company is the 3rd largest pharmaceutical player in the US by prescriptions (IQVIA MAT Jun 2019); 3rd largest Indian pharmaceutical company by global revenues (31st Mar 2019, Bloomberg LTM); 5th largest generic pharmaceutical player in Japan and 6th largest company in the Indian Pharmaceutical Market (IQVIA MAT Jun 2019).

For the financial year ended 31st 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

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

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For further information or queries please contact –

Pooja Thakran
VP – Corporate Communications
Email: poojathakran@lupin.com
Ph: +91-22-66402531 / 8291013225

Arvind Bothra
Head – Investor Relations
Email: arvindbothra@lupin.com
Ph: +91-22-66408237

**Safe Harbor Statement*

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