

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 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

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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.