



February 10, 2025

National Stock Exchange of India Limited

Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051

Symbol: LUPIN

BSE Limited

P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
Mumbai - 400 001

Scrip Code: Equity - 500257

Subject: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').

Dear Sir/Madam,

We are pleased to enclose a Press Release as regards, the Company and its alliance partner Natco Pharma Limited ('Natco') having received an approval from the U.S. FDA for Natco's Abbreviated New Drug Application for Bosentan Tablets for Oral Suspension, 32 mg, to market a generic equivalent of Tracleer® Tablets for Oral Suspension of Actelion Pharmaceuticals US, Inc.

The same is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

**AMIT KUMAR GUPTA
COMPANY SECRETARY & COMPLIANCE OFFICER
(ACS -15754)**

Encl: a/a.

LUPIN LIMITED

Registered Office: 3rd 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

Lupin and Natco Receive Approval from U.S. FDA for Bosentan Tablets for Oral Suspension

Mumbai, Naples, February 10, 2025: Global pharma major Lupin Limited (Lupin) and its alliance partner Natco Pharma Limited (Natco), today announced that they have received an approval from the United States Food and Drug Administration (U.S. FDA) for Natco's Abbreviated New Drug Application (ANDA) for Bosentan Tablets for Oral Suspension, 32 mg, to market a generic equivalent of Tracleer® Tablets for Oral Suspension of Actelion Pharmaceuticals US, Inc. Natco is the exclusive first-to-file for this product and is eligible for 180 days exclusivity.

Bosentan Tablets for Oral Suspension are indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Bosentan Tablets for Oral Suspension (RLD Tracleer®) had estimated annual sales of USD 11 million in the U.S. (IQVIA MAT December 2024).

About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 22,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions. To know more, visit www.lupin.com or follow us on LinkedIn <https://www.linkedin.com/company/lupin>

For further information or queries please contact –

Rajalakshmi Azariah

Vice President & Global Head – Corporate Communications, Lupin
rajalakshmi.azariah@lupin.com

***Safe Harbor Statement**

Tracleer® is a registered trademark of Actelion Pharmaceuticals US, Inc.