



Natco Pharma Limited

Regd. Off. : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad - 500034.
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

10th February, 2025

Corporate Relationship Department
M/s. BSE Limited
Dalal Street, Fort
Mumbai 400001

The Manager - Listing
M/s. National Stock Exchange of India Ltd
"Exchange Plaza", Bandra – Kurla Complex
Bandra (E) Mumbai 400051

Scrip Code: 524816

Scrip Code: NATCOPHARM

Dear Sir/Madam,

Sub:- Disclosure under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

With reference to the above cited subject, please find enclosed herewith the Press Release under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

This is for your information and records.

Thanking you,

Yours faithfully,
For NATCO Pharma Limited

Ch. Venkat Ramesh
Company Secretary &
Compliance Officer

NATCO Pharma Ltd

Natco House
Road No.2, Banjara Hills
Hyderabad-500 034, India

NATCO and its alliance partner Lupin announces approval of its Abbreviated New Drug Application (ANDA) for Bosentan Tablets for Oral Suspension (generic of Tracleer®)

Hyderabad, India, February 10th, 2025: NATCO Pharma Limited (BSE: 524816 and NSE: NATCOPHARM) ("NATCO") today announces final approval of its ANDA for Bosentan tablets for oral suspension (TFOS), 32mg, a generic version of Tracleer® by Actelion Pharmaceuticals US Inc. NATCO's marketing partner for the ANDA, Lupin Pharmaceuticals, Inc. (Lupin) will market the product in the U.S.

NATCO believes it has sole First-to-File status for the product and is eligible for a 180-day exclusivity at the time of launch. Launch details are bound by confidentiality. Bosentan TFOS is 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 (TFOS), 32mg had estimated sales of USD 11 million in the U.S. for 12 months ending Sep'24 as per industry sales data.

**Safe Harbor Statement*

All brand names and trademarks are the property of their respective owners

About NATCO Pharma Limited

NATCO Pharma Limited, (NSE:NATCOPHARM, BSE: 524816, Reuters: NATP.NS, Bloomberg: NTCPH,) headquartered at Hyderabad, India, develops, manufactures and distributes generic and branded pharmaceuticals, specialty pharmaceuticals, active pharmaceutical ingredients and crop protection products. The Company is a R&D oriented, and a science driven leading Oncology player in the targeted therapies of domestic market and focuses on limited competition molecule in the US. The Company has 9 manufacturing sites and 2 R&D facilities in India. The Company's manufacturing facilities are approved by several leading regulatory authorities like U.S. FDA, Brazil ANVISA, Health Canada, WHO and others catering to 50+ global markets. For more information, please visit us at www.natcopharma.com.

For further information or queries please contact:

Rajeev Menon – Manager, Investor Relations
Email: r.menon@natcopharma.co.in

Rajesh Chebiyam – EVP, Crop Health Sciences
Email: investors@natcopharma.co.in

Follow us on:

X (formerly Twitter): https://twitter.com/pharma_natco

LinkedIn: <https://www.linkedin.com/company/natcopharma>