



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

June 4, 2019

Corporate Relationship Department
M/s. BSE Ltd.
Dalal Street, Fort
Mumbai 400 001

Manager – Listing
M/s. National Stock Exchange of India Ltd
“Exchange Plaza”, Bandra – Kurla Complex
Bandra (E) Mumbai 400 051

Scrip Code: 524816

Scrip Code: NATCOPHARM

Dear Sir

Please find enclosed the Press Release for your information.

Thanking you

Yours faithfully
For NATCO Pharma Limited

A handwritten signature in black ink, appearing to read "M. Adinarayana".

M. Adinarayana
Company Secretary &
Vice President (Legal and Corp Affairs)



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Ref :PR/5/2019

Press Release

Hyderabad, 4th June, 2019

Natco files ANDA for Bosentan 32mg Tablets for the USA market

Hyderabad, India, June 4th, 2019

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) is pleased to announce its submission of an Abbreviated New Drug Application (ANDA) with Para IV certification with U.S. Food and Drug Administration (FDA) for the generic version of Bosentan 32mg tablets for oral suspension.

Bosentan 32mg tablets are sold by Actelion Pharmaceuticals US, Inc. (acquired by Johnson & Johnson), under the brand Tracleer®. NATCO believes that its ANDA is possibly the sole first-to-file based on the filing date. We further believe that our ANDA may be eligible for 180 days of marketing exclusivity at the time of potential launch of the product.

Tracleer® is indicated for the treatment of pulmonary arterial hypertension. As per Johnson & Johnson's annual report, for the year ending 2018, Tracleer® had registered sales of approx. \$268million in the US market, and the 32 mg is one strength that is indicated for pediatric patients.

Forwarded for favour of publication
For NATCO Pharma Limited

M Adinarayana

CS. M. Adinarayana
Company Secretary &
Vice President (Legal & Corp Affairs)