



Natco Pharma Limited

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21st November, 2024

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

With reference to the above cited subject, pursuant to the provisions of Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we would like to inform you that the Company has submitted the Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Risdiplam for Oral Solution.

In this regard, please find enclosed herewith the Press Release.

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

Hyderabad, India, November 21st, 2024: Natco Pharma Limited (BSE: 524816 and NSE: NATCOPHARM) ("NATCO") today announced submission of Abbreviated New Drug Application (ANDA) for Risdiplam for Oral Solution

Submission of Abbreviated New Drug Application (ANDA)

NATCO is pleased to announce its submission of an Abbreviated New Drug Application (ANDA) containing a paragraph IV certification with the U.S. Food and Drug Administration (FDA) for the generic version of EVRYSDI (Risdiplam) 0.75 mg/mL For Oral Solution. EVRYSDI® is the brand of Genentech Inc.

NATCO believes it is amongst one of the first two companies to have filed a substantially-complete ANDA containing a paragraph IV certification for this product and expects to be eligible for 180 days of shared marketing exclusivity at the time of potential launch of the generic product under certain circumstances. NATCO has been named as one of the defendants in a lawsuit filed in the United States District Court for the District of New Jersey by Genentech, Inc., Hoffmann-La Roche Inc., and PTC Therapeutics, Inc.

EVRYSDI® has recorded sales of USD 571 million in the US market for the year 2023*.

Risdiplam for Oral Solution is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

*brand sales (annual report)

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 US 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:

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