



## 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

January 31, 2019

Corporate Relationship Department  
M/s. BSE Ltd.  
Dalal Sreet, 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 enclose herewith the Press Release for your information.

Thanking you

Yours faithfully  
For NATCO Pharma Limited

A handwritten signature in black ink that reads "M. Adinarayana".

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



## 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

Ref:PR/11/2019

Press Release

### NATCO and Alvogen file ANDA for Ibrutinib Tablets for the USA market

**Hyderabad, India, January 31<sup>st</sup>, 2019**

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) 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 generic version of Ibrutinib Tablets of 140mg, 280mg, 420mg and 560mg strength (proposed generic equivalents to Imbruvica® Tablets).

NATCO and its co-development & marketing partner, Alvogen Pine Brook LLC, USA, believe that the ANDA is possibly sole first-to-file based on the ANDA filing dates. We further believe that our ANDA may be eligible for 180 days of marketing exclusivity at the time of potential launch of the product under certain circumstances.

In the United States Imbruvica® brand is owned and marketed by Pharmacyclics LLC and Janssen Biotech, Inc. Imbruvica® had U.S. Sales of approximately US\$ 2.6 Billion for twelve months ending September, 2018, according to data from IQVIA. As per the last tracked prescription sales, almost 83% of the sales contribution has come from the above mentioned tablet dosage forms.

---

Forwarded for favour of publication

For NATCO Pharma Limited

*M. Adinarayana*

— M. Adinarayana  
Company Secretary &

Vice President (Legal and Corp Affairs)