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June 14<sup>th</sup>, 2021

Corporate Relationship Department M/s. BSE Ltd. Dalal Street, Fort <u>Mumbai 400 001</u> Manager – Listing M/s. National Stock Exchange of India Ltd "Exchange Plaza", Bandra – Kurla Complex Bandra (E) <u>Mumbai 400 051</u>

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

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



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Press Release

## NATCO receives approval for Carfilzomib Vials ANDA (generic for KYPROLIS<sup>®</sup>) in the US market

## Hyderabad, India, June 14<sup>th</sup>, 2021

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) is pleased to announce that its marketing partner, Breckenridge Pharmaceutical Inc. (BPI), has received approval for its Abbreviated New Drug Application (ANDA) for Carfilzomib Vials ANDA (generic for KYPROLIS<sup>®</sup>), from the U.S. Food and Drug Administration (USFDA).

The parties have received final approval for 10mg and 60mg strengths of the product and tentative approval for 30mg strength of the product. Based on the ANDA filing date NATCO believes that it is eligible for 180 days of sole generic marketing exclusivity for the 10mg strength and shared 180 days of generic marketing exclusivity for the 60mg strength of the product at the time of launch.

In the year 2019, the parties have reached a Settlement Agreement on para IV litigation related to the product with Onyx Therapeutics, Inc. By virtue of the settlement, NATCO and Breckenridge have been granted a license permitting the launch of their generic carfilzomib products on a date that is held as confidential in the year 2027 or sooner depending on certain occurrences.

As per industry sales data, KYPROLIS<sup>®</sup> had generated annual sales of \$696million during the twelve months ending December 2020 in the US. 10mg strength alone generated sales of \$63million for the same period.

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

Forwarded for favor of publication For NATCO Pharma Limited

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