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Natco Pharma submits ANDA for Ibrutinib generic

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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.

Natco Pharma Limited has announced 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. According to the company, the 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.