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NATCO announces USFDA Filing for Sorafenib Tablets, 200mg

Hyderabad, India, February 11th, 2015

Natco Pharma Limited (NSE: NATCOPHARM; BSE: 524816) announced today that its marketing partner, Mylan Inc. (Nasdaq:MYL), has filed an Abbreviated New Drug Application (ANDA) for Sorafenib Tablets, 200mg, with the U.S. Federal Drug Administration (USFDA). This product is the generic version of NEXAVAR®, which is indicated for the treatment of certain types of cancers including unresectable hepatocellular carcinoma and advanced renal cell carcinoma.

Natco and its marketing partner believe that they are the first to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity upon receiving final FDA approval.

Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals Inc., and Onyx Pharmaceuticals Inc., sells Sorafenib Tablets, 200mg, under Brand name NEXAVAR®, in the USA market. For the 12 months ending Dec. 31, 2014, NEXAVAR® had U.S. sales of approximately $48 million, according to IMS Health.

Forwarded for favour of publication
For NATCO Pharma Limited

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