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NATCOs marketing partner, Mylan Inc., files ANDA for Three Times Per Week Generic Copaxone® 40 mg/mL

Hyderabad, India, August 30th, 2014

Natco Pharma Limited (NSE: NATCOPHARM) announced today that its marketing partner in the USA, Mylan Inc. (Nasdaq: MYL), has filed an Abbreviated New Drug Application (ANDA) for a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL) and has been accepted by the U.S. Food and Drug Administration (US FDA). COPAXONE® is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Natco's partner Mylan believes it is one of the first 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 marketing exclusivity in the U.S. upon final FDA approval.

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. Copaxone 40 mg/mL had U.S. sales of approximately $411.5 million for the 12 months ending June 30, 2014, according to IMS Health.

Forwarded for favor of publication

For NATCO Pharma Limited

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