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Natco files ANDA for Bosentan 32mg Tablets

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Tracleer® is indicated for the treatment of pulmonary arterial hypertension

Natco Pharma Limited is pleased to announce its submission of an Abbreviated New Drug Application (ANDA) with Para IV certification with U.S. Food and Drug Administration (FDA) for the generic version of Bosentan 32mg tablets for oral suspension.

Bosentan 32mg tablets are sold by Actelion Pharmaceuticals US, Inc. (acquired by Johnson & Johnson), under the brand Tracleer®. NATCO believes that its ANDA is possibly the sole first-to-file based on the filing date. We further believe that our ANDA may be eligible for 180 days of marketing exclusivity at the time of potential launch of the product.

Tracleer® is indicated for the treatment of pulmonary arterial hypertension. As per Johnson & Johnson's annual report, for the year ending 2018, Tracleer® had registered sales of approx. $268million in the US market, and the 32 mg is one strength that is indicated for pediatric patients.