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Natco Pharma Limited announced that its marketing partner in the USA, Breckenridge Pharmaceutical, Inc., has filed an Abbreviated New Drug Application (ANDA) for Bendamustine Hydrochloride powder; IV infusion (25mg/vial and 100mg/vial).

Breckenridge's ANDA includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the drug before expiration of the '190, '524, and '863 patents. Natco and Breckenridge believe that the ANDA was filed on the first-to-file date, providing 180 days of exclusivity.

Teva (Cephalon) sells Bendamustine Hydrochloride under Brand name TREANDA, used as a chemotherapy medicine in oncology segment. The market size of Bendamustine Hydrochloride in the USA is approximately US\$660M for twelve months ending September 2013, according to IMS Health