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Singapore: Mylan Institutional business has received final approval from the US Food and Drug Administration (FDA) for Mylan's abbreviated new drug application (ANDA) for preservative-free Thiamine Hydrochloride Injection, multiple-dose vials. This product is indicated for the treatment of thiamine deficiency.

Thiamine Hydrochloride Injection had US sales of approximately $18.6 million for the 12 months ending March 31, 2012, according to IMS Health. Mylan is shipping this product, presented in 25-vial packs, immediately.

In other news, Mylan also confirmed that it has been sued by Pfizer, Wyeth LLC, Wyeth Pharmaceuticals, and PF Prism C V in connection with the filing of an ANDA with the US FDA for Desvenlafaxine Succinate extended-release tablets. This product is the generic version of Pfizer's Pristiq tablets, which are indicated for the treatment of major depressive disorder

(MDD) in adults.

Mylan said it was one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for both strengths and expects to share 180 days of marketing exclusivity upon final FDA approval. The plaintiffs filed the lawsuit in the US District Court for District of Delaware.

Currently, Mylan has 169 ANDAs pending FDA approval representing $83.9 billion in annual sales, according to IMS Health. Thirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $25.6 billion in annual brand sales. Pristique Tablets had total sales of approximately $559.4 million in the last 12 months, according to IMS Health.