

## Mylan launches sleep and depression-related drugs

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**Singapore:** Mylan Pharmaceuticals received final approval from the US FDA for its abbreviated new drug application (ANDA) for Modafinil tablets, 100 mg and 200 mg and for Lithium Carbonate extended-release tablets USP, 450 mg.

While Modafinil is the generic version of Cephalon's Provigil tablets and is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder, the Lithium Carbonate extended-release tablets is indicated for the treatment of episodes of manic depressive illness.

Ms Heather Bresch, CEO, Mylan, while speaking about the launch of Modafinil, said that, "Mylan is pleased to bring a generic version of Provigil Tablets to the US market prior to the expiration of the first-filer's 180-day marketing exclusivity period. This launch represents Mylan's continued commitment to expanding access to high quality, more affordable medicine, and we are pleased to do our part in helping to meet patients' unmet needs."

According to IMS Health, Modafinil recorded US sales of approximately \$1.3 billion for the 12 months ending June 30, 2012; and Lithium Carbonate extended-release tablets witnessed US sales of approximately \$15.2 million for the 12 months ending June 30, 2012.

Currently, Mylan has 166 ANDAs pending FDA approval representing \$78.4 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$25.1 billion in annual brand sales, for the 12 months ending December 31, 2011.