

Mylan launches generic hypertension drug in US

10 July 2014 | Regulatory | By BioSpectrum Bureau



Singapore: Global pharmaceutical firm, Mylan, has launched Telmisartan tablets-20 mg, 40 mg and 80 mg, the generic version of Boehringer Ingelheim's Micardis tablets, in US.

Mylan received final approval from US Food and Drug Administration (FDA) for its abbreviated new drug application (ANDA) for this product, which is indicated for the treatment of hypertension, to lower blood pressure.

Telmisartan tablets, 20 mg, 40 mg and 80 mg, had US sales of approximately \$259.2 million for the 12 months ending March 31, 2014, according to IMS Health.

Currently, Mylan has 305 ANDAs pending FDA approval representing \$107.2 billion in annual brand sales, according to IMS Health. 42 of these pending ANDAs are potential first-to-file opportunities, representing \$25 billion in annual brand sales, for the 12 months ending December 31, 2013, according to IMS Health.