

Mylan launches generic of Pfizer's antifungal drug

01 October 2013 | News | By BioSpectrum Bureau



Singapore: US-based Mylan Pharmaceuticals has launched generic version of Pfizer's Vfend, Voriconazole for Oral Suspension, 40 mg/mL.

Mylan was the first company to have filed a substantially complete ANDA containing a Paragraph IV patent certification for Voriconazole for Oral Suspension, 40 mg/mL. The company received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product and was awarded 180 days of marketing exclusivity.

Mr Heather Bresch, CEO, Mylan commented, "Mylan's launch of Voriconazole for Oral Suspension, 40 mg/mL, supports the company's mission to expand access to high quality medicine by bringing to market the first, low-cost generic version of this product. We are committed to continuing to develop, manufacture and market a broad range of generic pharmaceuticals, including specialty, niche products such as this one."

Voriconazole for Oral Suspension, 40mg/mL, is a triazole antifungal drug and, according to IMS Health, had US sales of approximately \$17.1 million for the 12 months ending June 30, 2013.

Currently, Mylan has 178 ANDAs pending FDA approval representing USD83.8 billion in annual sales, according to IMS Health. Forty two of these pending ANDAs are potential first-to-file opportunities, representing \$23.8 billion in annual brand sales, for the 12 months ending December 31, 2012, according to IMS Health.