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Glenmark's new generic granted tentative ANDA approval

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Glenmark Pharmaceuticals USA (Glenmark) has been granted tentative approval by the United States Food and Drug Administration (US FDA) for its Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg, the generic version of Vimpat Tablets, 50 mg, 100 mg, 150 mg and 200 mg of UCB.

Glenmark will market this product upon receiving final approval of its Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg ANDA. The patent listed in the Orange Book for Vimpat Tablets, 50 mg, 100 mg, 150 mg and 200 mg is scheduled to expire on March 17, 2022.

According to IMS Health sales data for the 12 month period ending September 2015, the Vimpat market achieved annual sales of approximately $691.0 million.

Glenmark's current portfolio consists of 102 products authorized for distribution in the US marketplace and 64 ANDA's pending approval with the U.S. FDA.