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Glenmark receives tentative ANDA approval for MS drug

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Glenmark Pharmaceuticals receives tentative ANDA approval for Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg

Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, a generic version of Tecfidera®1 Capsules, 120 mg and 240 mg, of Biogen Inc. It is used for treating multiple sclerosis.

According to IQVIATM sales data for the 12 month period ending August 2019, the Tecfidera® Capsules, 120 mg and 240 mg market2 achieved annual sales of approximately $3.7 billion.

Glenmark's current portfolio consists of 161 products authorized for distribution in the U.S. marketplace and 49 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.