

Glenmark receives tentative ANDA approval for generic Zytiga

23 January 2019 | News

Glenmark's current portfolio consists of 148 products authorized for distribution in the U.S. marketplace and 54 ANDA's pending approval with the U.S. FDA



Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Abiraterone Acetate Tablets USP, 250 mg, a generic version of Zytiga®1 Tablets, 250 mg, of Janssen Biotech, Inc.

According to IQVIATM sales data for the 12 month period ending November 2018, the Zytiga® Tablets, 250 mg market2 achieved annual sales of approximately \$1.3 billion.

Glenmark's current portfolio consists of 148 products authorized for distribution in the U.S. marketplace and 54 ANDA's pending approval with the U.S. FDA.