Press Release

Zydus Cadila receives tentative approval from USFDA for Brexpiprazole Tablets

Ahmedabad, India, 9 September, 2021

Zydus Cadila has received tentative approval from the USFDA to market Brexpiprazole Tablets in the strength of 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg. (US RLD: Rexulti Tablets). Brexpiprazole is an atypical antipsychotic indicated for use as an adjunctive therapy to antidepressants for the treatment of Major Depressive Disorder (MDD) and for treatment of schizophrenia. The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad.

The group now has 321 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is dedicated to creating healthier communities globally.

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