

## **Zydus receives final approval and 180 days shared exclusivity from the USFDA for Cariprazine Capsules**

*Ahmedabad, India, 12 September, 2022*

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received final approval from the United States Food and Drug Administration (USFDA) to market Cariprazine Capsules, USP 1.5 mg, 3 mg, 4.5 mg, and 6 mg (USRLD: VRAYLAR®).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Cariprazine Capsules, 1.5 mg, 3 mg, 4.5 mg, and 6 mg and therefore is eligible for 180 days of shared generic drug exclusivity for Cariprazine Capsules, 1.5 mg, 3 mg, 4.5 mg, and 6 mg.

Cariprazine is an atypical antipsychotic indicated for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Cariprazine Capsules had annual sales of USD 2.39 bn in the United States according to IQVIA MAT July 2022.

The group now has 322 approvals and has so far filed over 428\* ANDAs since the commencement of the filing process in FY 2003-04.

*(\*as of 30<sup>th</sup> June 2022)*

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**PRESS  
RELEASE**

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