Zydus receives tentative approval from USFDA for Olaparib Tablets, 100 mg and 150 mg

Ahmedabad, India, 07 November, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) for Olaparib Tablets, 100 mg and 150 mg (USRLD: Lynparza Tablets, 100 mg and 150 mg).

Olaparib is indicated for treatment of certain types of ovarian, breast, pancreatic, and prostate cancers in patients who have specific genetic mutations (specifically in the BRCA gene or other homologous recombination repair [HRR] genes). Olaparib tablets will be produced at Zydus Lifesciences Ltd, SEZ. Olaparib tablets had annual sales of USD 1,379.4 mn in the United States (IQVIA MAT Sept-2025).

The group now has 426 approvals and has so far filed 487* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 30-Sept-25)*

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878