Zydus receives final and tentative Approval from the USFDA for Tofacitinib Tablets, 5 mg and 10 mg, respectively

- *Tofacitinib Tablets is also eligible to receive 180 days of shared exclusivity for its 5 mg strength.*

Ahmedabad, India, 21 March, 2023

Zydus Lifesciences Limited's (including its subsidiaries/affiliates, hereinafter referred to as "Zydus") subsidiary Zydus Pharmaceuticals (USA) Inc. has received final approval for Tofacitinib Tablets, 5 mg and tentative approval for Tofacitinib Tablets, 10 mg (USRLD: Xeljanz® Tablets) from the United States Food and Drug Administration (USFDA).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Tofacitinib Tablets, 5 mg and therefore is eligible for 180 days of shared generic drug exclusivity for Tofacitinib Tablets, 5 mg.

Tofacitinib is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis and for the treatment of adult patients with active psoriatic arthritis. It is also indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Tofacitinib Tablets, 5 mg and 10 mg had annual sales of USD 900 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 352 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

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PRESS RELEASE

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