Zydus Cadila gets 180-day exclusivity for Tofacitinib extended-release 22 mg tablets, announces final approval from USFDA

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Zydus Cadila has received final approval from the USFDA to market Tofacitinib extended-release tablets, 11 mg and 22 mg in the United States (ANDA-214264 and US RLD: XELJANZ XR). Zydus was the first ANDA filer on Tofacitinib extended-release tablets 22 mg and currently holds 180-day exclusivity on this strength.

Tofacitinib extended-release tablets had annual sales of approximately $2,082 million in the United States for the year ending June 2021 according to IQVIA data. 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 Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies including small molecule drugs, biologic therapeutics, and vaccines. The group employs 25,000 people worldwide and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com/

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