

Zydus receives Final Approval from the USFDA for Indomethacin Suppository with Competitive Generic Therapy (CGT) designation

- *The company has been granted 180-day CGT exclusivity to market this product*

Ahmedabad, India, 03, August, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) to manufacture and market Indomethacin suppositories, 50mg. Zydus' Indomethacin suppositories, 50 mg is the generic version of the Reference Listed Drug (RLD) Indocin® suppositories. Zydus has been granted a CGT designation by the USFDA for its Indomethacin suppositories. Zydus' Indomethacin suppositories also been granted 180-day CGT exclusivity to market this product.

"We are happy to leverage the CGT approval pathway of the USFDA to provide patients with expanded access to a product with limited competition," said Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Limited. He further added, "The achievements of our team who have worked on the development, filing and manufacturing of Indomethacin suppositories reflects our ongoing commitment to bring complex generic products accessible to patients who need them the most."

Indomethacin suppositories is a non-steroidal, anti-inflammatory drug indicated for moderate to severe rheumatoid arthritis including acute flares of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) and acute gouty arthritis. Indomethacin suppositories 50mg had an annual sales of approximately USD 95 mn in the United States (IQVIA MAT April-2023).

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 24000 people worldwide and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.



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