Zydus receives Prior Approval Supplement (PAS) approval from USFDA for Mycophenolate Mofetil for Injection USP

Ahmedabad, India, 21March, 2022

Zydus Lifesciences Limited (formerly known as Cadila Healthcare Ltd.) has received Prior Approval Supplement (PAS) approval from the USFDA to market Mycophenolate Mofetil for Injection USP, 500 mg/vial (US RLD: CellCept injection). The injection will be manufactured at the group's injectables manufacturing facility at Jarod near Vadodara in Gujarat. The Prior Approval Supplement (PAS) was for a site transfer into the Jarod site. This site was recently inspected by the USFDA. Earlier, in September 2017, the group was granted approval to market Mycophenolate Mofetil for Injection in the strength of 500 mg/vial. Mycophenolate Mofetil is indicated for use in combination with other drugs i.e., cyclosporine and corticosteroids for the prophylaxis of organ rejection in patients receiving renal, hepatic or cardiac transplants.

The group now has 330 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

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 over 23000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.

PRESS RELEASE

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Prior Approval Supplement (PAS)

A Prior Approval Supplement (PAS) is an application which seeks to make changes to an already approved application, such as an Abbreviated New Drug Application (ANDA), which is used by USFDA to approve generic drugs.

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