Zydus receives final approval from the USFDA for Balsalazide Disodium Capsules USP, 750 mg

Ahmedabad, India, 10 June, 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) for Balsalazide Disodium Capsules USP, 750 mg (USRLD: Colazal Capsules, 750 mg).

Balsalazide Disodium is used to treat bowel diseases like ulcerative colitis. It helps reduce symptoms of ulcerative colitis such as diarrhea, rectal bleeding, and stomach pain. Balsalazide belongs to a class of drugs known as aminosalicylates and works by reducing swelling in the colon. The product will be manufactured at the group's formulation manufacturing facility in SEZ, Ahmedabad (India).

Balsalazide Disodium Capsules USP, 750 mg had annual sales of USD 29 mn in the United States (IQVIA MAT April 2023).

The group now has 372 approvals and has so far filed over 442* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st March 2023)

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PRESS RELEASE

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