



October 12, 2026

BSE Limited

P J Towers,
Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated October 12, 2026, titled **“Zydus Therapeutics Presents New Post Hoc Analysis of Phase 3 EPICS-III Trial at ACG 2026 Showing Greater Biochemical Response With Investigational Saroglitazar Compared to Placebo Across Geographic Subgroups in PBC”**.

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Yours faithfully,

For, **Zydus Lifesciences Limited**

DHAVAL Digitally signed
by DHAVAL
NARENDRA SONI
Date: 2026.10.12
17:43:52 +05'30'
NARENDRA
A SONI

Dhaval N. Soni

Company Secretary and Compliance Officer
Membership No. FCS7063

Encl.: As above

Zydus Lifesciences Limited

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Zydus Therapeutics Presents New Post Hoc Analysis of Phase 3 EPICS-III Trial at ACG 2026 Showing Greater Biochemical Response With Investigational Saroglitazar Compared to Placebo Across Geographic Subgroups in PBC

- *Numerically higher biochemical response treatment difference was observed in the U.S. subgroup relative to the non-U.S. subgroup (Δ 60.7% vs. Δ 41.6%) in patients with primary biliary cholangitis (PBC)*
- *Findings build on the clinical profile of saroglitazar in patients with PBC who have inadequate response or intolerance to ursodeoxycholic acid (UDCA)*

Ahmedabad, India and Pennington, N.J. October 12, 2026

[Zydus Therapeutics](#) Inc. (“Zydus Therapeutics”), a wholly owned subsidiary of Zydus Lifesciences Limited, a global innovation-led healthcare company, today shared new analyses from the pivotal EPICS-III Phase 2(b)/3 clinical trial of saroglitazar in adult patients with PBC in a late-breaking oral presentation at the American College of Gastroenterology (ACG) 2026 Annual Meeting. Saroglitazar is an investigational product that has not been approved by the U.S. Food and Drug Administration (FDA); its safety and effectiveness have not been established.

The presentation, delivered by Raj Vuppalanchi, MD, Professor of Medicine at Indiana University School of Medicine and Global Principal Investigator for the EPICS-III study, shared a post hoc exploratory analysis of geographic subgroups investigating whether treatment effects observed with saroglitazar are consistent across regions, with particular focus on U.S. versus non-U.S. patients. More details on the full results of the EPICS-III trial, a Phase 3 randomized, double-blind, placebo-controlled study evaluating saroglitazar in adult patients with PBC who had an inadequate response to or intolerance of UDCA, in which nearly thirty percent of patients were from the U.S., were provided in a press release earlier this year and were presented at the EASL Congress 2026.

The U.S. population compared 28 patients treated with saroglitazar to 14 placebo-treated patients; the composite non-U.S. population (consisting of Argentina, Iceland, and Turkey) compared 69 patients treated with saroglitazar to 37 patients treated with placebo. In the results of this exploratory analysis, composite biochemical response rates were greater with saroglitazar than placebo in both U.S. (60.7% vs. 0%) and non-U.S. subgroup regions (55.1% vs. 13.5%). A larger unstratified treatment difference was observed between saroglitazar and placebo in the U.S. subgroup (Δ 60.7%) versus the non-U.S. subgroup (Δ 41.6%). ALP normalization treatment difference rates at Week 52 were not substantially different between the U.S. and non-U.S. subgroups (7.7% vs. 9.6%); ALP normalization was defined as ALP<116 U/L. One additional U.S. participant in the saroglitazar group did not achieve normalization



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but had an ALP value of 117 U/L at Week 52. ALP change from baseline was numerically greater in patients receiving saroglitazar in both subgroups at Week 52, with a larger treatment difference in the U.S. subgroup (-104 vs. 62.2; Δ -166.2 U/L) relative to the non-U.S. subgroup (-110.9 vs. -6.2; Δ -104.7 U/L). In EPICS-III, saroglitazar was generally well tolerated, with adverse events generally balanced between saroglitazar-treated and placebo-treated patients. The most common adverse reactions experienced by saroglitazar-treated patients enrolled in EPICS-III were pruritus, headache and urinary tract infection.

“These findings provide additional insight into the Phase 3 EPICS-III results and the biochemical responses observed among patients enrolled in different geographic regions,” said Raj Vuppalachchi. “While this was a post hoc analysis and the findings should be interpreted accordingly, we believe it is important to continue evaluating the EPICS-III data to better understand the results across the study population.”

Zydus Therapeutics is developing saroglitazar for the treatment of PBC in combination with UDCA in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Saroglitazar is currently under review by the FDA. If approved, Zydus Therapeutics plans to launch saroglitazar in the United States by March 2027.

Three additional non-U.S. participants in the saroglitazar group did not achieve normalization but had ALP values of 118, 119, and 120 U/L at Week 52. Composite biochemical response was defined as achieving the following at Week 52: ALP < 1.67 x ULN, $\geq$ 15% decrease in ALP from baseline, and total bilirubin $\leq$ ULN or direct bilirubin $\leq$ ULN in subjects with known Gilbert's syndrome.

About Primary Biliary Cholangitis (PBC):

PBC is a rare, progressive autoimmune disease that gradually destroys the bile ducts, resulting in an accumulation of bile in the liver, which can result in fibrosis, cirrhosis, the need for liver transplantation, or death. PBC is characterized by increases in biochemical markers, particularly alkaline phosphatase (ALP) and bilirubin. Clinical symptoms include pruritus (itching) and fatigue, both of which can be severe.

About the EPICS-III Trial:

EPICS-III is a multicenter, randomized, double-blind, placebo-controlled, seamless Phase 2(b)/3 trial evaluating the efficacy and safety of saroglitazar in patients with PBC who had an inadequate response to or intolerance of UDCA. After optimal dose selection, the Phase 3 trial randomized 148 patients in a 2:1 ratio to saroglitazar magnesium 1 mg (equivalent to 0.97 mg saroglitazar and 0.03 mg magnesium) or placebo.



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About Saroglitazar:

Saroglitazar is a novel Peroxisome Proliferator-Activated Receptor (PPAR) α/γ agonist, currently under investigation as a treatment for patients with PBC. Its distinct biological profile targets both bile acid toxicity and liver inflammation. Saroglitazar has received Orphan Drug Designation, Fast Track Designation, and Priority Review from the U.S. Food and Drug Administration for the treatment of PBC.

About Zydus Therapeutics:

Zydus Therapeutics, a wholly owned subsidiary of Zydus Lifesciences Ltd., is a clinical-stage, specialty-focused biopharmaceutical company dedicated to developing transformative treatments for rare and serious liver diseases, including PBC and Metabolic Dysfunction-Associated Steatohepatitis (MASH). The company is headquartered in Pennington, New Jersey. For more information, visit www.zydustx.com.

About Zydus Lifesciences:

Zydus Lifesciences Ltd., 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 30,000 people worldwide, including 1,500 scientists engaged in R&D, 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. Over the last decade, Zydus has introduced several innovative, first-in-class products in the market to address unmet healthcare needs with vaccines, therapeutics, biologicals, and New Chemical Entities. For more details, visit www.zyduslife.com.

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Forward-Looking Statements:

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements about future regulatory plans and the potential of saroglitazar. These statements are based on current expectations and are subject to risks and uncertainties. Actual results could differ. Zydus Therapeutics does not commit to updating any of these statements unless required by law.



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