May 28, 2026

BSE Limited **Code: 532321**
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited **Code: Zyduslife**
Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated May 28, 2026, titled **"Zydus Therapeutics' New Drug Application (NDA) for Saroglitazar to treat Primary Biliary Cholangitis (PBC) granted Priority Review by the US FDA"**.

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 NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2026.05.28 17:52:16 +05'30'

Dhaval N. Soni
Company Secretary and Compliance Officer
Membership No. FCS7063

Encl.: As above

Zydus Therapeutics' New Drug Application (NDA) for Saroglitazar to treat Primary Biliary Cholangitis (PBC) granted Priority Review by the US FDA

EPICS-III trial Phase 3 results demonstrated significant biochemical response; data to be presented as a late-breaking presentation at EASL Congress 2026.

- *US FDA granted Priority Review and assigned PDUFA target action date of November 27, 2026.*
- *In the EPICS-III trial Phase 3 results, saroglitazar met the primary endpoint of biochemical response, with 56.7% of patients treated with saroglitazar achieving biochemical response versus 9.8% of patients receiving placebo, a treatment difference of 48% (95% CI: 35.3, 60.8) ($p < 0.001$).*
- *Saroglitazar demonstrated a treatment difference of 40.1% in mean alkaline phosphatase (ALP) levels, reducing ALP by 33.5% versus a 6.5% increase among patients receiving placebo.*
- *If approved, Zydus Therapeutics plans to launch saroglitazar in the United States in Q4 of FY 27.*

Ahmedabad, India, 28 May 2026

Zydus Therapeutics, a wholly owned subsidiary of Zydus Lifesciences Limited, a global innovation-led health care company, today announced that the US Food and Drug Administration (US FDA) granted Priority Review to the New Drug Application (NDA) for saroglitazar. The proposed indication is for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The US FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 27, 2026. Priority Review directs US FDA attention and resources to applications for drugs that, if approved, may provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions.

"The acceptance of our NDA with Priority Review highlights the significant unmet need that exists for patients with PBC and represents an important step in the path to making saroglitazar available in the US," said Managing Director of Zydus Lifesciences, Dr. Sharvil Patel. "We look forward to collaborating with the US FDA during the NDA Priority Review process and will, in parallel, continue to build our medical affairs and commercialization capabilities towards a potential US launch in the fourth quarter of FY 27."

The NDA is supported by the EPICS-III trial Phase 3 results, a randomized, double-blind, placebo-controlled study evaluating saroglitazar in adult patients with PBC who had an inadequate response to or intolerance of UDCA. The EPICS-III trial Phase 3 results will be presented as a late-breaking session at the European

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878

Association for the Study of the Liver (EASL) Congress in Barcelona, Spain on Saturday, May 30, 2026.

"EPICS-III is a registrational study that tested saroglitazar as a second-line treatment in patients with PBC. The study met its primary endpoint, demonstrating a clinically meaningful biochemical response, along with a favorable safety and tolerability profile," said Raj Vuppalanchi, MD, Professor of Medicine at Indiana University School of Medicine and Global Principal Investigator for the EPICS-III study.

In the trial (N = 148), saroglitazar met its primary endpoint at Week 52, demonstrating a statistically significant improvement in biochemical response compared to placebo. A total of 56.7% of patients treated with saroglitazar achieved biochemical response compared with 9.8% of patients receiving placebo, a treatment difference of 48% (95% CI: 35.3, 60.8) ($p < 0.001$). Among participants with baseline ALP ≤ 3 x ULN, biochemical response was 83.1% and 14.7%, respectively. Composite biochemical response was defined as achieving the following at 12 months: ALP < 1.67 x ULN, ≥ 15% decrease in ALP from baseline, and total bilirubin ≤ ULN or direct bilirubin ≤ ULN in subjects with known Gilbert's syndrome.

Patients randomized to receive saroglitazar had a mean baseline ALP level of 363 U/L, compared with 317.2 U/L in the placebo arm. At Week 52, saroglitazar demonstrated a treatment difference of -124.1 U/L (-40.1%) in least-squares mean change from baseline in ALP, with patients receiving saroglitazar achieving a -115.4 U/L (-33.5%) reduction from baseline compared with a +8.8 U/L (+6.5%) increase from baseline among patients receiving placebo.

"The magnitude of separation between saroglitazar and placebo in biochemical response is a clinically meaningful result for patients whose disease continues to progress on UDCA," said Dr. Kris Kowdley, Director, Liver Institute Northwest; Professor, Elson S. Floyd. College of Medicine, Washington State University; Senior Scientific Advisor and Medical Director, Velocity Clinical Research. "Achieving meaningful reductions in ALP is an important treatment goal in PBC as it is a surrogate marker predictive of long-term outcomes. These results suggest saroglitazar may provide a promising therapeutic option for patients with a suboptimal response to UDCA alone, when ALP continues to rise above target."

As a secondary endpoint, at Week 24, patients treated with saroglitazar also experienced a statistically significant reduction in pruritus compared to placebo, with a change from baseline in 5-D Itch Total score of -5.9 versus -2.7, a treatment difference of -3.2 (95% CI: -5.66, -0.82) ($p = 0.009$). At Week 52, saroglitazar-treated patients experienced a reduction of -4.6 compared with -4.4 on placebo, which was not statistically significant.

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Saroglitazar was generally well-tolerated in the EPICS-III trial. Most treatment-emergent adverse events (TEAEs) were mild to moderate in nature. Serious adverse events were reported in 6.3% of patients in the saroglitazar group versus 11.1% in the placebo group. None were considered related to study treatment by the investigators, and there were no treatment-related deaths. TEAEs occurring in >5% of patients and at least 2% more frequently on saroglitazar versus placebo were headache, hypertension, upper respiratory tract infection, abdominal pain, COVID-19, diarrhea, and vitamin D deficiency.

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 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 ursodeoxycholic acid (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.

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 US FDA for the treatment of PBC, reflecting its potential to address the significant unmet need in patients who do not adequately respond to current therapies. The US FDA has assigned a Prescription Drug User Fee Act target action date of November 27, 2026.

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.

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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 29,000 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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