Kezar Life Sciences Announces Presentation of PORTOLA Data at the American Association for the Study of Liver Disease (AASLD) – The Liver Meeting® 2025

November 7, 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 7, 2025-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases, today announced two presentations from the completed Phase 2a PORTOLA clinical trial in patients with autoimmune hepatitis (AIH) at The Liver Meeting 2025 held by the American Association for the Study of Liver Disease (AASLD) and taking place November 7-11, in Washington, DC. The presentation details are as follows:

- **Oral Presentation Title:** Zetomipzomib, a First-in-Class Selective Immunoproteasome Inhibitor, Demonstrates Steroid Sparing Biochemical Remission in Patients with Relapsed or Insufficiently Responding Autoimmune Hepatitis in a Randomized, Double-blind, Placebo-controlled, Phase 2a Study
- **Presenter:** Craig Lammert, MD, Associate Professor of Medicine, Indiana University School of Medicine and Director, Autoimmune Hepatitis Association
- **Date and Time:** November 10, 2025, 2:00pm-2:15pm ET
- **Key Findings:**
  - In steroid-dependent patients, 36% of patients treated with zetomipzomib achieved biochemical remission and were able to taper their daily steroid dose to AASLD treatment guideline levels of ≤ 5 mg/day, compared to 0% in the placebo group.
  - No patients achieving a complete response with zetomipzomib flared during treatment, including those patients continuing zetomipzomib therapy in the open-label extension.
  - Zetomipzomib was generally well-tolerated. The most common adverse events were mild to moderate injection site reactions, and there were fewer infections reported in the zetomipzomib group relative to the placebo treated patients.

- **Poster Presentation Title:** Analysis of Circulating Biomarkers in the Randomized, Double-Blind, Placebo-Controlled PORTOLA Phase 2a Study Evaluating Zetomipzomib, a Selective Immunoproteasome Inhibitor, in Patients with Autoimmune Hepatitis
- **Presenter:** Janet Anderl, Principal Scientist, Biology
- **Date and Time:** November 10, 2025, 8:00am-5:00pm ET (presentation at 1:00-2:00pm ET)
- **Key Findings:**
  - Zetomipzomib administration led to meaningful biomarker changes across both the innate and adaptive immune pathways in patients with AIH.
  - Reductions in immunoglobulins, B cells and monocytes, along with increases in regulatory T cells, were observed in participants achieving a complete response.
  - Biomarker shifts, including decreases in neutrophil proteins linked to liver inflammation and increases in TGF-ß1 and chemokines, correlated with clinical responses.
  - The biomarker profile with zetomipzomib in patients with AIH was consistent with patterns previously seen in SLE, reinforcing its potential mechanism of action.

Kezar also announced an oral presentation of safety and preliminary efficacy from its PALIZADE Phase 2b clinical trial of zetomipzomib in patients with lupus nephritis (LN) at the American Society of Nephrology (ASN) Kidney Week taking place November 5-9, in Houston, TX. The presentation details are as follows:

- **Oral Presentation Title:** Safety and Preliminary Efficacy of Zetomipzomib from the PALIZADE Phase 2b Clinical Trial in Patients with Lupus Nephritis
- **Presenter:** Samir V. Parikh, MD, Associate Professor of Medicine, Division of Nephrology, The Ohio State University Wexner Medical Center
- **Date and Time:** November 7, 2025, 5:40 – 5:50 PM CT
- **Key findings:**
  - At Week 25, zetomipzomib 60 mg treatment resulted in 42% of LN patients achieving a urine protein to creatinine ratio (UPCR) of ≤ 0.5, compared to 21% in the placebo arm.
  - Treatment with zetomipzomib 60 mg was associated with a 64% reduction in lupus disease activity (SLEDAI-2K) from Baseline at Week 25 and induced deeper reductions in anti-dsDNA autoantibody levels, compared to either placebo or zetomipzomib 30 mg.

- Analysis of safety data indicates an overall similar profile between zetomipzomib 30 mg and 60 mg and consistent with global studies in LN.

About Zetomipzomib

Zetomipzomib is a novel, first-in-class, selective immunoproteasome inhibitor with broad therapeutic potential across multiple autoimmune diseases. Preclinical research demonstrates that selective immunoproteasome inhibition results in a broad anti-inflammatory response in animal models of several autoimmune diseases, while avoiding immunosuppression. Data generated from completed clinical trials provide evidence that zetomipzomib exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases.

About PORTOLA

PORTOLA is a placebo-controlled, randomized, double-blind Phase 2a clinical trial evaluating the efficacy and safety of zetomipzomib in patients with AIH that are insufficiently responding to standard of care or have relapsed. The study has completed enrollment of 24 patients, randomized (2:1) to receive 60 mg of zetomipzomib or placebo in addition to background therapy for 24 weeks, with a protocol-suggested steroid taper. The primary efficacy endpoint will measure the proportion of patients who achieve a complete biochemical response by Week 24 measured as normalization of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and Immunoglobulin G (IgG) values (if elevated at baseline), with steroid dose levels not higher than baseline.

About Autoimmune Hepatitis

Autoimmune hepatitis (AIH) is a rare chronic disease in which the immune system attacks the liver and causes inflammation and tissue damage, severely impacting patients' physical health and quality of life. Lifelong maintenance therapy is required to avoid relapse and burdensome adverse effects. If left untreated, AIH can lead to cirrhosis, liver failure and hepatocellular carcinoma. In the United States, AIH affects approximately 100,000 individuals, with incidence rates increasing. The cause of this condition remains unclear, with females affected four times as often as males. Currently, standard of care treatment for AIH is chronic, immunosuppressive treatment with corticosteroids that frequently cause life-altering side effects, including diabetes, osteoporotic fractures and cataracts. There is a significant need for treatment regimens that reduce or remove the need for chronic immunosuppression from using corticosteroids.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated in a Phase 2a clinical trial for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. For more information, visit www.kezarlifesciences.com, and follow us on LinkedIn, Facebook, Twitter and Instagram.

Cautionary Note on Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "can," "should," "expect," "believe," "potential," "anticipate" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Kezar's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause Kezar's clinical development programs, future results or performance to differ materially from those expressed or implied by the forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the likelihood that data will support future development and therapeutic potential, the association of data with treatment outcomes and the likelihood of obtaining regulatory approval of Kezar's product candidates. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, difficulties enrolling and conducting our clinical trials, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Kezar's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Kezar assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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