Kezar Life Sciences Announces FDA Has Lifted Partial Clinical Hold on PORTOLA Phase 2a Trial Evaluating Zetomipzomib for the Treatment of Patients with Autoimmune Hepatitis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 15, 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 that the Division of Hepatology and Nutrition of the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on the completed PORTOLA Phase 2a clinical trial evaluating zetomipzomib, a first-in-class selective immunoproteasome inhibitor, in patients with autoimmune hepatitis (AIH).

"We are pleased that the FDA has lifted the partial clinical hold on zetomipzomib in AIH after their review of our comprehensive safety assessment of the zetomipzomib program," said Chris Kirk, PhD, CEO and co-founder of Kezar. "We continue to believe that zetomipzomib has the potential to positively transform the lives of patients living with AIH. We look forward to engaging with the FDA to align on the design of the next clinical trial of zetomipzomib in AIH."

Although Kezar has suspended development of zetomipzomib in lupus nephritis (LN) to focus on AIH, the company met with the Independent Data Monitoring Committee (IDMC) for the previously terminated PALIZADE clinical trial to review the safety profile of zetomipzomib. The IDMC has provided Kezar with recommendations for conducting future clinical trials in LN. Based on this feedback and internal analysis of safety data across all clinical studies involving zetomipzomib, Kezar plans to respond to the FDA Division of Rheumatology and Transplant Medicine with a request to lift the clinical hold on zetomipzomib 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 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 use of 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 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 timing and outcome of regulatory submissions and interactions with the FDA, EMA or any other regulatory agencies with respect to zetomipzomib or Kezar's clinical trials, the initiation of an additional clinical trial of zetomipzomib in AIH, and expectations regarding the removal of the clinical hold of zetomipzomib in LN, and the likelihood of obtaining regulatory approval of zetomipzomib. 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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