Kezar Life Sciences Announces Positive IDMC Safety Review of PORTOLA Trial of Zetomipzomib in Patients with Autoimmune Hepatitis and Provides PALIZADE Update

October 17, 2024

- *PORTOLA Phase 2a clinical trial in patients with autoimmune hepatitis (AIH) to continue without modification following review by Independent Data Monitoring Committee (IDMC); reiterating guidance of topline data in first half 2025*
- *PALIZADE Phase 2b clinical trial in patients with active lupus nephritis (LN) will be discontinued; focusing resources on clinical development of zetomipzomib in AIH*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 17, 2024-- 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 key clinical development updates.

The IDMC overseeing the PORTOLA Phase 2a clinical trial of zetomipzomib in patients with AIH recommended that the trial may proceed without modification following its third scheduled meeting. The IDMC examined safety data from all patients enrolled in the trial, including data from patients who completed the blinded treatment period and continued to the open-label extension portion of the trial which includes an additional 24 weeks of treatment. Three members of the IDMC, including the committee chair, are also members of the IDMC overseeing the PALIZADE study of zetomipzomib in LN. To date, no Grade 4 or 5 serious adverse events (SAEs) have been observed in the PORTOLA trial which is being conducted at clinical sites in the United States. Kezar has completed enrollment of PORTOLA and plans to report topline data in the first half of 2025.

Kezar has also made the strategic decision to terminate the PALIZADE Phase 2b clinical trial in patients with active LN and focus clinical development efforts of zetomipzomib in AIH, a rare disease with a significant unmet medical need. PALIZADE was recently placed on clinical hold following the recommendation of the IDMC after its assessment of four Grade 5 (fatal) SAEs that occurred in patients enrolled in the Philippines and Argentina (including one patient on placebo). Kezar will unblind the trial and perform a full investigation into all safety events from the study. As of termination, 84 patients were enrolled, and Kezar will report available data from PALIZADE at a later date.

“The IDMC recommendation to continue the PORTOLA trial without modification strengthens our confidence in the potential for zetomipzomib to be a meaningful treatment for patients living with autoimmune hepatitis,” said Chris Kirk, PhD, Kezar’s Chief Executive Officer. “While we are disappointed to discontinue our development program in LN, we would like to thank the investigators, patients and their families for their participation in the PALIZADE trial. This decision was difficult given the favorable safety profile and clinical activity data we have presented from the MISSION study and rapid enrollment to PALIZADE. However, a focused development effort in AIH extends our cash runway and provides flexibility as we work to bring zetomipzomib forward as a treatment for patients living with this life-threatening disease.”

Kezar’s unaudited cash position is approximately $148 million, including cash, cash equivalents and marketable securities, as of September 30, 2024. This cash estimate is a preliminary estimate and based on information currently available to management, and this estimate could change.

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 140,000 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. For more information, visit www.kezarlifesciences.com, and follow us on LinkedIn, Facebook, Twitter and Instagram.

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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,” “plans,” “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 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 nature, frequency and severity of adverse events; the design, progress and outcome of Kezar's clinical trials; Kezar's ability to report data from its clinical trials on expected timelines, if at all; and Kezar's ability to extend its cash runway. Many factors may cause differences between current expectations and actual results, including those factors that 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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Investor and Media Contact:
Gitanjali Jain
Senior Vice President, Investor Relations and External Affairs
Kezar Life Sciences, Inc.
gjain@kezarbio.com

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