Kezar Life Sciences Announces Cessation of Enrollment and Dosing in the Phase 2b PALIZADE Trial of Zetomipzomib in Active Lupus Nephritis Patients

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 30, 2024-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing a novel small molecule to treat unmet needs in immune-mediated diseases, today announced the voluntary cessation in enrollment of new patients and dosing of ongoing patients in the Phase 2b PALIZADE clinical trial, pending further evaluation. PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose levels of zetomipzomib in patients with active lupus nephritis (LN). Patients in the trial are randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy.

To date, 84 patients have been enrolled in the PALIZADE trial, and patient safety data are reviewed by an Independent Data Monitoring Committee (IDMC). Kezar has suspended enrollment and dosing in PALIZADE at the recommendation of the IDMC after their recent review of emerging safety data, including an assessment of four Grade 5 (fatal) serious adverse events (SAEs) that have occurred during the course of the trial in patients enrolled in the Philippines and Argentina. Review of the data by the IDMC revealed that three of the fatalities showed a common pattern of symptoms and proximity to dosing, and additional non-fatal SAEs showed a similar proximity to dosing. Kezar remains blinded as to which patients were on the zetomipzomib or placebo treatment arms. Kezar has not observed any instances of death or serious opportunistic infections in prior clinical studies of zetomipzomib.

Kezar's ongoing Phase 2a PORTOLA clinical trial of zetomipzomib in patients with autoimmune hepatitis has completed enrollment and remains active at this time. To date, no Grade 4 or 5 SAEs have been observed in the PORTOLA clinical trial.

Kezar's decision to pause enrollment and dosing on PALIZADE enables time to evaluate the totality of data regarding the SAEs and determine next steps and potential risk mitigation strategies. The Company has notified all study investigators and is notifying regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, of its decision. At this time, a formal Investigational New Drug clinical hold has not been issued. If Kezar receives a clinical hold letter from the FDA, it will review the content and determine next steps.

"Our top priority is the safety of every patient who participates in our clinical trials," said Chris Kirk, PhD, Kezar's Chief Executive Officer. "Lupus nephritis represents a life-threatening medical condition in need of new therapies. We will continue to work with the site investigators to learn more about each of these cases and hope to have an informed discussion with the IDMC and regulatory authorities as we look to continue the zetomipzomib development program in lupus nephritis and autoimmune hepatitis. We will provide additional information regarding this investigation and the zetomipzomib development program at the appropriate time."

About Lupus Nephritis

Lupus nephritis (LN) is one of the most serious complications of systemic lupus erythematosus (SLE). LN is a disease comprising a spectrum of vascular, glomerular and tubulointerstitial lesions and develops in approximately 50% of SLE patients within 10 years of their initial diagnosis. LN is associated with considerable morbidity, including an increased risk of end-stage renal disease requiring dialysis or renal transplantation and an increased risk of death. There are limited approved therapies for the treatment of LN. Management typically consists of induction therapy to achieve remission and long-term maintenance therapy to prevent relapse.

About PALIZADE

PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53. The primary efficacy endpoint is the proportion of patients who achieve a complete renal response (CRR) at Week 37, including a urine protein-to-creatine ratio (UPCR) of 0.5 or less without receiving rescue or prohibited medications.

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 2b clinical trial for lupus nephritis and a Phase 2a clinical trial for autoimmune hepatitis. 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 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; the Company's ability to complete its clinical trials on expected timelines, if at all; and the timing and outcome of regulatory submissions and actions by the FDA, EMA or any other regulatory agencies with respect to zetomipzomib or Kezar's clinical trials. 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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