Kezar Life Sciences Announces Clinical Hold of Zetomipzomib IND for Treatment of Lupus Nephritis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 4, 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 that it was informed via teleconference with the U.S. Food and Drug Administration (FDA) that the zetomipzomib Investigational New Drug (IND) application for the treatment of lupus nephritis (LN) has been placed on clinical hold. This action follows Kezar's communication to the FDA that Kezar was voluntarily suspending enrollment and dosing in its Phase 2b PALIZADE clinical trial of zetomipzomib in patients with active LN at the recommendation of the trial's Independent Data Monitoring Committee (IDMC). The IDMC's recommendation followed their 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. The FDA indicated that they will provide an official clinical hold letter to Kezar within 30 days.

"We are steadfastly committed to patient safety and have directed our efforts to investigating these cases as we look to continue the zetomipzomib development program," said Chris Kirk, PhD, Kezar's Chief Executive Officer. "At this time, our zetomipzomib IND for the treatment of autoimmune hepatitis is unaffected. Our Phase 2a PORTOLA clinical trial of zetomipzomib in patients with autoimmune hepatitis remains active, and we have not observed any Grade 4 or 5 SAEs in the PORTOLA trial to date."

About 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 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.

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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