Kezar Life Sciences Announces Regulatory Update on Zetomipzomib Program in Autoimmune Hepatitis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 9, 2026-- 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 Food and Drug Administration (FDA) Division of Hepatology and Nutrition has granted Kezar a Type C meeting for the first quarter to discuss the development of zetomipzomib, a novel, selective inhibitor of the immunoproteasome, in patients with autoimmune hepatitis (AIH).

The Type C meeting will involve review of a potential global, randomized Phase 2b clinical study of zetomipzomib in patients with relapsed and refractory AIH. As part of the briefing package submitted to the FDA, Kezar submitted pharmacokinetic and hepatic safety data analyses from previously conducted clinical trials to support a proposal for parallel AIH and hepatic impairment studies. Kezar also submitted additional safety data and an updated risk-mitigation plan aimed to modify the previous requirement issued from the FDA to require 48-hour in-unit patient monitoring in future AIH studies.

“We appreciate the opportunity to collaborate with the FDA on key clinical trial parameters for a well-powered study of zetomipzomib in patients with AIH, a population with significant unmet medical need and currently without FDA-approved therapies,” said Chris Kirk, PhD, CEO of Kezar Life Sciences. “The additional safety and pharmacokinetic data analysis performed in response to prior FDA feedback further support our belief that zetomipzomib has the potential to change the treatment landscape in this serious disease. Furthermore, achieving alignment with the FDA on endpoints and trial conduct would provide a clear development pathway for this novel therapy and potentially unlock value for our shareholders as we continue to evaluate strategic alternatives.”

As previously disclosed, Kezar has retained TD Cowen to support the company with its ongoing strategic review process focusing on maximizing shareholder value, and which included a significant workforce reduction and other cost-containment and cash conservation measures.

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, X and Instagram.

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 using corticosteroids.

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 regarding: the timing and outcome of regulatory submissions and interactions with the FDA or any other regulatory agencies with respect to zetomipzomib or Kezar’s clinical trials; the possibility of achieving alignment with the FDA on endpoints and clinical trial conduct; the potential value of the company as part of its strategic review process; the design, initiation, progress, timing, scope and results of ongoing and potential future clinical trials; the potential of zetomipzomib to be the first approved agent in AIH; and Kezar’s evaluation of strategic alternatives available to maximize shareholder value. Many factors may cause differences between current expectations and actual results, including the significant workforce reduction and cost-containment measures implemented by Kezar, unexpected safety or efficacy data observed during clinical studies, 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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