Kezar Life Sciences Announces Regulatory Update on Zetomipzomib Program in Autoimmune Hepatitis and Plans to Explore Strategic Alternatives

October 16, 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 16, 2025-- Kezar Life Sciences, Inc. (Nasdaq: KZR, the Company), a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases, today announced regulatory updates and the initiation of a process to explore a full range of strategic alternatives focused on maximizing shareholder value. The Company has retained TD Cowen to support it with the strategic review process.

Kezar has been unable to align with the Food and Drug Administration (FDA) on a potential registrational clinical trial of zetomipzomib, a novel, selective inhibitor of the immunoproteasome, in patients with relapsed and refractory autoimmune hepatitis (AIH). The FDA Division of Hepatology and Nutrition cancelled a Type C meeting that was previously scheduled with Kezar in the fourth quarter to discuss a proposed study in AIH. Autoimmune hepatitis is a rare, chronic disease that if left untreated, can lead to cirrhosis, liver failure and hepatocellular carcinoma. In the United States, AIH affects approximately 100,000 individuals, predominantly women. There are no FDA-approved therapeutics for AIH and few industry-sponsored clinical trials. Current therapy involves life-long use of corticosteroids and immunosuppressive agents, which results in an increased risk of infections, malignancies, diabetes, osteoporotic fractures and cataracts.

In March 2025, Kezar reported positive safety and efficacy data from PORTOLA, the first successfully completed, randomized clinical trial in patients with refractory or relapsed AIH. Final data from PORTOLA will be presented as an oral presentation at The Liver Meeting® 2025, on November 10th in Washington, DC, by Dr. Craig Lammert, Associate Professor of Medicine at Indiana University School of Medicine and Executive Director for the Autoimmune Hepatitis Association.

Kezar submitted a comprehensive report to the FDA that integrated safety, efficacy and pharmacology data across more than 300 patients and healthy volunteers enrolled to zetomipzomib clinical trials, as well as a risk mitigation plan for out-patient monitoring for future trials that was modeled after approved injectable therapeutics. In their written response, the FDA requested that Kezar conduct a stand-alone study to define the pharmacokinetics of zetomipzomib in subjects with significant hepatic impairment prior to the initiation of another clinical trial in AIH. Notably, Kezar informed the FDA that they would exclude AIH patients with significant hepatic impairment in the proposed registration-enabling study. This interim study required by the FDA would delay future trials of zetomipzomib in AIH by approximately 2 years. In addition, the FDA has required future clinical trials of zetomipzomib to include 48-hour patient monitoring in a clinical research unit, which would likely hinder patient enrollment and participation.

“We are incredibly disappointed with the unusual decision by the FDA to cancel our Type C meeting, which we had hoped would allow us to align on key clinical trial parameters for a potentially registration-enabling 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. “We remain deeply committed to patient safety and had provided the FDA with pharmacokinetic data of zetomipzomib in AIH patients with mild hepatic impairment, a plan for conducting a parallel pharmacokinetic study in subjects with hepatic impairment, and a robust risk mitigation plan for future clinical trials. While we remain excited about the potential of zetomipzomib to be the first approved agent in AIH, we lack the resources to extend the development timeline and question the technical feasibility, medical need and patient burden of utilizing an in-unit monitoring program in AIH clinical trials. I want to thank everyone on the team here at Kezar, as well as the physicians, staff and patients who participated in our clinical trials for their commitment to bringing zetomipzomib forward as a novel therapy in autoimmune hepatitis.”

Plans to Explore Strategic Alternatives

In connection with the evaluation of strategic alternatives, the Company will be implementing a restructuring plan including a workforce reduction and other cost-containment and cash conservation measures. The Company intends to retain employees essential for supporting value creation as part of its strategic review.

There can be no assurance that this process will result in the Company pursuing a transaction or any other strategic outcome. The Company has not set a timetable for completion of the process for evaluating strategic alternatives and does not intend to disclose further developments or guidance on the status of its programs or the process for evaluating strategic alternatives unless and until it is determined that further disclosure is appropriate or necessary.

As of September 30, 2025, the Company’s cash, cash equivalents and marketable securities totaled approximately $90.2 million. This preliminary estimate is not a comprehensive statement of the Company’s financial results for the quarter ended September 30, 2025, and has not been audited, reviewed or compiled by its independent registered public accounting firm. The Company’s actual consolidated cash, cash equivalents and marketable securities balance as of September 30, 2025, may differ from these estimates due to the completion of the Company’s quarter-end closing procedures.

Extension of Limited Duration Shareholder Rights Plan to Protect Integrity of Process

In addition, the Company’s Board of Directors (the Board) has adopted an amendment (the Amendment) to its existing limited duration stockholder rights plan (as amended, the Rights Plan) to extend the duration of the Rights Plan, effective immediately.

The extended Rights Plan is intended to protect the interests of the Company and its stockholders, help ensure that all interested parties have the opportunity to participate fairly in the strategic review process and to provide the Board time to make informed decisions. The Board did not adopt the extension to the Rights Plan in response to a specific takeover threat. In addition, the Rights Plan does not prevent the Board from engaging with parties or accepting an acquisition proposal, if the Board believes that it is in the best interests of Kezar and all of its stockholders.

The Rights Plan, as amended, will automatically expire on the day following the certification of the voting results of the Company's 2026 annual meeting of stockholders or, if at such meeting the Company's stockholders approve or ratify the Rights Plan, the day following the certification of the voting results of the Company's 2027 annual meeting, unless the rights are earlier redeemed or exchanged by the Company. Except as otherwise set forth in the Amendment, the terms of the Rights Plan are unchanged and remain in full force and effect.

Additional information regarding the Rights Plan is contained in the Company's Form 8-K filed with the U.S. Securities and Exchange Commission (SEC) on October 17, 2024, and in the Company's Form 8-K filed with the SEC on December 3, 2024. Additional information regarding the Amendment will be contained in an additional Form 8-K filing.

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 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, EMA or any other regulatory agencies with respect to zetomipzomib or Kezar's clinical trials; the design, initiation, progress, timing, scope and results of ongoing and potential future clinical trials; the impact of the FDA's request for a stand-alone study to define the pharmacokinetics of zetomipzomib in subjects with hepatic impairment prior to the initiation of another clinical trial in AIH; the potential of zetomipzomib to be the first approved agent in AIH; Kezar's evaluation of strategic alternatives available to Kezar to maximize stockholder value; the ability of the Rights Plan to protect the interests of Kezar and its stockholders, help ensure that all interested parties have the opportunity to participate fairly in the strategic review process and to provide the Board time to make informed decisions; Kezar's cash, cash equivalents, and marketable securities; and Kezar's ability to retain employees essential for supporting value creation as part of its strategic review. 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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