Kezar Life Sciences Receives FDA Clearance of IND for Zetomipzomib for the Treatment of Autoimmune Hepatitis

October 3, 2022

Company to host a virtual Research and Development Day during the fourth quarter 2022

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 3, 2022-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration for zetomipzomib, its first-in-class, selective immunoproteasome inhibitor, for the treatment of autoimmune hepatitis (AIH).

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. Females are affected four times as often as males. Standard of care treatment for AIH is immunosuppressive treatment with chronic corticosteroids that can lead to additional morbidity and mortality. There is a significant need for treatment regimens that reduce or remove the need for chronic immunosuppression using corticosteroids.

The PORTOLA trial (KZR-616-208) is a randomized, double-blind, placebo-controlled Phase 2a clinical trial evaluating the safety and efficacy of zetomipzomib in patients with AIH that are insufficiently responding to standard of care or have relapsed. The target enrollment will be 24 patients, who will be randomly assigned (2:1) to receive either zetomipzomib with prednisone or placebo with prednisone for 24 weeks, with a protocol-directed steroid taper by Week 14. The primary efficacy endpoint will measure the proportion of patients who achieve a complete response measured as normalization of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels with a successful corticosteroid taper by Week 24.

"Zetomipzomib is a unique small molecule with the potential to be a non-immunosuppressive, anti-inflammatory treatment for multiple autoimmune diseases. We plan to run PORTOLA, an early proof-of-concept study in parallel to our other development efforts, including a late-phase efficacy trial for patients with lupus nephritis and a potential program in patients with systemic lupus erythematosus," said Noreen R. Henig, M.D., Kezar's Chief Medical Officer. "Autoimmune hepatitis is a disease where there is a good fit between the pathophysiology of the disease and mechanism of action of zetomipzomib, as well as significant unmet medical need and few alternative therapies. We are grateful to the Autoimmune Hepatitis Association for their support of the patients and families with AIH and their connection to dedicated physicians and researchers in autoimmune liver disease."

"Patients with autoimmune hepatitis need new therapies that can better treat their disease. Lifelong maintenance therapy is required for most patients with AIH and an alternative regimen that reduces or removes the need for immunosuppression with corticosteroids would be welcomed by patients and the medical community," commented Craig Lammert, M.D., Assistant Professor of Medicine at Indiana University and Executive Director of the Autoimmune Hepatitis Association.

About Zetomipzomib (KZR-616)

Zetomipzomib (KZR-616) 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 Phase 1 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 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 using corticosteroids.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders. The company is pioneering first-in-class, small-molecule therapies that harness master regulators of cellular function to inhibit multiple drivers of disease via single, powerful targets. Zetomipzomib, its lead development asset, is a selective immunoproteasome inhibitor being evaluated in Phase 2 clinical trials in lupus nephritis, dermatomyositis and polymyositis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. KZR-261 is the first anti-cancer clinical candidate from the company's platform targeting the Sec61 translocon and the protein secretion pathway. An open-label dose-escalation Phase 1 clinical trial of KZR-261 to assess safety, tolerability and preliminary tumor activity in solid tumors is underway. For more information, visit www.kezarlifesciences.com.

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,” “should,” “expect,” “believe”, “plan” 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 about the design, progress, timing, scope and results of clinical trials, the anticipated regulatory development and future clinical trials involving Kezar’s product candidates, the likelihood that data will support future development and therapeutic potential, the association of data with treatment outcomes and the likelihood of obtaining regulatory approval of Kezar’s product candidates. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, changes in expected or existing competition, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20221003006001/en/

Investor Contact:
Gitanjali Jain
Vice President, Investor Relations and External Affairs
gjain@kezarbio.com

Media Contact:
Julia Deutsch
Solebury Strategic Communications
jdeutsch@soleburystrat.com

Source: Kezar Life Sciences, Inc.