



Kezar Highlights Broad Therapeutic Potential of KZR-616 During ACR Convergence 2020

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Clinical and pre-clinical data continues to support potential of KZR-616 to positively effect multiple drivers of immune-mediated diseases

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Kezar Life Sciences, Inc.](#) (Nasdaq: [KZR](#)), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today highlighted the broad therapeutic potential of KZR-616, a first-in-class immunoproteasome inhibitor, in two poster sessions during the [American College of Rheumatology Annual Meeting \(ACR Convergence 2020\)](#). Both posters can be found on [Kezar's website](#) under the "Science" section.

Richard Furie, M.D., Chief, Division of Rheumatology, Northwell Health in New York, is presenting [updated results from the MISSION Phase 1b study](#) (NCT03393013) evaluating KZR-616 in patients with systemic lupus erythematosus (SLE) with and without lupus nephritis (LN). The presentation by Dr. Furie includes additional patient-weeks of safety and tolerability data compared to prior data presentations. Encouraging trends in early efficacy signals continue, including improvement of SLE-specific disease activity scores. No new safety signals have been observed, and KZR-616 administered subcutaneously (SC) once weekly has been consistently well tolerated for 13 weeks. KZR-616 has been studied at doses of 45 mg, 60 mg and 75 mg SC weekly. Previously, Kezar has identified 45 mg and 60 mg as likely therapeutic doses to advance in its clinical development program.

Kezar's collaborator, Marta Del Rio Oliva, Ph.D. candidate of the University of Konstanz, is presenting an [evaluation of KZR-616 in a well-accepted preclinical mouse model of inflammatory myositis](#). In this model of myositis, KZR-616 treatment was associated with significant improvement in muscle function and reduced levels of muscle tissue damage. It is also demonstrated that an active immunoproteasome is necessary for the disease to occur. These data suggest that selective inhibition of the immunoproteasome with KZR-616 could have a meaningful clinical impact in patients with inflammatory myopathies, such as dermatomyositis (DM) and polymyositis (PM). Kezar is actively enrolling the PRESIDIO Phase 2 study (NCT04033926), a placebo-controlled, cross-over study of patients with DM and PM. The open-label extension study for PRESIDIO is also enrolling.

"These two presentations strengthen our understanding of how KZR-616 can be an effective treatment for patients with a variety of autoimmune diseases. The preclinical data show the importance of the immunoproteasome in the pathology of myositis and the ability of KZR-616 to selectively inhibit this important regulator of immune function for therapeutic benefit. The clinical data continues to show that KZR-616 is well-tolerated and improves multiple signs and symptoms of SLE. We continue to build a strong foundation for KZR-616 as a novel and important therapeutic for patients living with LN, dermatomyositis and polymyositis and other immune-mediated diseases," said Noreen Henig, M.D., Kezar's Chief Medical Officer.

About MISSION

MISSION (NCT03393013) is a Phase 1b/2 clinical trial evaluating KZR-616 in SLE patients with and without nephritis. The study consists of two parts. The Phase 1b portion is an open-label dose escalation study which is evaluating doses up to 75 mg of KZR-616 across 6 cohorts, which has completed enrollment. The primary objective of the Ph1b portion of MISSION is to assess safety and tolerability. Secondary objectives include evaluating pharmacokinetics (PK) and pharmacodynamics (PD) and selecting dose levels for the Phase 2 trials. Several exploratory efficacy measures are also being assessed: Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), Cutaneous Lupus Erythematosus Severity Index-Activity (CLASI-A), Tender and Swollen Joint Counts (TJC/SJC), Physician Global Assessment (PhGA), Patient Global Assessment (PtGA) and Patient Assessment of Pain (PtP). The Phase 2 portion of the MISSION study evaluating KZR-616 in patients with LN is currently enrolling.

About PRESIDIO

PRESIDIO (NCT04033926) is a Phase 2 randomized, double-blind, placebo-controlled, crossover, multicenter study to evaluate the safety, tolerability, efficacy, PK and PD of treatment with KZR-616 in patients with active polymyositis or dermatomyositis. During the 32-week treatment period, patients will receive either KZR-616 or placebo subcutaneously once weekly for 16 weeks followed by a crossover to the other treatment arm for an additional 16 weeks. The study is expected to enroll 24 patients. An open-label extension study of PRESIDIO is now also enrolling.

About KZR-616

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 1a and 1b trials provide evidence that KZR-616 exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases. Phase 2 trials are underway in severe autoimmune diseases.

About Kezar Life Sciences

Based in South San Francisco, Kezar Life Sciences is combining courage, conviction and cutting-edge science to develop 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 and inhibit multiple drivers of disease via a single target. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe and underserved autoimmune diseases. Additionally, KZR-261, the first clinical candidate for the treatment of cancer from the company's protein secretion program targeting the Sec61 translocon, is undergoing IND-enabling activities. For more information, visit www.kezarlifesciences.com, and follow us on Twitter at [@KezarBio](#), [Facebook](#) and [LinkedIn](#).

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" 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 likelihood that data will support future development, the association of data with treatment outcomes, the design, progress, timing, scope and results of clinical trials, the anticipated timing of disclosure of results of clinical trials and the likelihood of obtaining regulatory approval of Kezar's product candidates. Many factors may cause differences between current expectations and actual results, including the impacts of the COVID-19 pandemic on the company's business, clinical trials and financial position, unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, 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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