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Kezar Highlights Data from MISSION Phase 1b Study of KZR-616 during the Pan American Congress of Rheumatology

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 data from the Phase 1b portion of the MISSION study demonstrating safety, tolerability and early efficacy signals of KZR-616 in patients with systemic lupus erythematosus (SLE) and lupus nephritis (LN) at the Pan-American Congress of Rheumatology (PANLAR 2020). The data were presented in a poster titled "Treatment of Systemic Lupus Erythematosus with the Immunoproteasome Inhibitor KZR-616: Results from the First 5 Cohorts of the MISSION Study, an Open-label Phase 1b Dose-Escalation Study" by study investigator Richard Furie, M.D., Chief, Division of Rheumatology, Northwell Health in New York. The poster can be found on Kezar's corporate website under the "Science" section.

"Lupus and lupus nephritis are life-threatening diseases that disproportionately impact young Latina women in the prime of their life, and there is an urgent need for new treatment options that can target the full spectrum of their disease and don't cause debilitating side effects that add to the disease burden," said Dr. Furie. "These encouraging early positive data suggest that the novel mechanism of KZR-616 has the potential to address the underlying drivers of inflammation, resulting in improvements across organ systems in this disease."

MISSION is a Phase 1b/2 study of KZR-616 in SLE patients with and without nephritis. The Phase 1b portion has completed enrollment in the final cohort, which is evaluating a 75 mg dose of KZR-616. The Phase 2 portion exclusively in LN is actively enrolling.

As of the May 4, 2020 data analysis, 39 patients were enrolled in the MISSION Phase 1b study across five dose cohorts evaluating 45 mg and step-up dosing to 60 mg weekly for 13 weeks. Patients are followed to week 25 and kept on stable background treatment. At this time point, 22 patients completed 13 weeks of treatment and are included in the exploratory efficacy measures reported below:

- Patients with increased DNA antibodies (serologic markers of SLE disease activity) at baseline that completed through week 25 of the study showed decreased titers following treatment.

Percent (%) Change from Baseline			
	Mean Anti-dsDNA Level, IU/mL (Baseline)	**End of Treatment (Week 13)**	**End of Study (Week 25)**
Patient A	1015	-64.0	-82.0

Patient B	87	-20.7	-33.3
Patient C	32	-6.3	-18.8
Patient D	134	-60.4	-54.5
Patient E	90	-76.7	-68.9

As previously reported:

- Notably, two of two patients with active proliferative LN, despite being on stable background therapy, saw a greater than 50% decrease from baseline in proteinuria, a biomarker of disease severity. Both patients also experienced reductions in SLEDAI-2K and reductions in anti-dsDNA (double-stranded DNA) antibody levels.
- Among patients completing treatment, all seven measures of disease activity improved (decrease in score) in the majority of patients from Baseline to Week 13. Improvement in disease activity persisted following the end-of-treatment.
- Step-up dosing of KZR-616 improved overall tolerability. Most patients had mild (87.2%) or moderate (30.8%) TEAEs, which occurred early and diminished with later doses. The most common treatment emergent adverse events were transient injection site reactions.
- To date, no patients have discontinued treatment in Cohorts 2b and 2c, which utilize a lyophilized formulation of KZR-616.

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 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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