Kezar Life Sciences Reports Second Quarter 2023 Financial Results and Provides Business Update

August 10, 2023

- *PALIZADE global Phase 2b clinical trial evaluating zetomipzomib in lupus nephritis and PORTOLA Phase 2a clinical trial evaluating zetomipzomib in autoimmune hepatitis are both open for enrollment*
- *KZR-261 dose escalation study continues to progress and display a favorable safety and tolerability profile*
- *Cash, cash equivalents and marketable securities totaled $236.6 million as of June 30, 2023*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 10, 2023-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune mediated and oncologic disorders, today reported financial results for the second quarter ended June 30, 2023 and provided a business update.

"This quarter, we've been laser-focused on executing on our three ongoing clinical trials to validate the broad potential of our product candidates," said John Fowler, Kezar's Co-Founder and Chief Executive Officer. "Now actively recruiting patients, our PALIZADE and PORTOLA clinical trials are designed to demonstrate zetomipzomib's potential to be a steroid-sparing, immunomodulating treatment for multiple autoimmune conditions. Our first-in-class protein secretion inhibitor, KZR-261, continues to demonstrate a favorable safety and tolerability profile as we proceed with our dose-escalation study, and represents only the first of several potential assets generated by our Sec61 translocon inhibition platform. I commend the Kezar team for their hard work and unwavering commitment to our mission of delivering novel treatments to patients fighting difficult-to-treat chronic diseases."

Zetomipzomib: Selective Immunoproteasome Inhibitor

PALIZADE – Phase 2b clinical trial of zetomipzomib in patients with active lupus nephritis (LN) (ClinicalTrials.gov: NCT05781750)

- PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose-levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53. The primary efficacy endpoint is the proportion of patients who achieve a complete renal response (CRR) at Week 37, including a urine protein-to-creatine ratio (UPCR) of 0.5 or less without receiving rescue or prohibited medications.

PORTOLA – Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis (AIH) who have not benefited from standard-of-care treatment (ClinicalTrials.gov: NCT05569759)

- PORTOLA is a placebo-controlled, randomized, double-blind Phase 2a clinical trial evaluating the efficacy and safety of zetomipzomib in patients with AIH that are insufficiently responding to standard of care or have relapsed. Target enrollment will be 24 patients, randomized (2:1) to receive 60 mg of zetomipzomib or placebo in addition to background corticosteroid therapy for 24 weeks, with a protocol-mandated 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.

MISSION – Completed open-label Phase 2 clinical trial of zetomipzomib in patients with active LN (ClinicalTrials.gov: NCT03393013)

- The post-hoc analysis across LN biopsy classes from the open-label Phase 2 MISSION clinical trial was presented as a poster presentation at the National Kidney Foundation (NKF) Spring Clinical Meeting 2023, which took place April 11-15, 2023 in Austin, Texas.
- The complete MISSION Phase 1b/2 results, along with a post hoc subgroup analysis in the Phase 2 Hispanic/Latino population, were presented as a poster presentation at the Pan American League of Associations for Rheumatology (PANLAR) 2023 Congress, which took place April 26-29, 2023 in Rio de Janeiro, Brazil.
- The complete MISSION Phase 1b/2 results were presented as an oral presentation at the LUPUS & KCR 2023 meeting, which took place May 17-20, 2023 in Seoul, Korea.
- The complete MISSION Phase 2 results, MISSION Phase 2 uCD163 data, and the unmet need of European patients with LN were presented as poster presentations at the European Alliance of Associations for Rheumatology (EULAR) 2023 Congress, which took place May 31 – June 3, 2023 in Milan, Italy.
- The post-hoc analysis of MISSION Phase 2 patients with nephrotic range proteinuria and the unmet need of European patients with LN were presented as oral presentations at the 60th European Renal Association (ERA) Congress, which took

place June 15-18, 2023 in Milan, Italy.

Protein Secretion Inhibition Platform

KZR-261: Broad-Spectrum Sec61 Translocon Inhibitor

KZR-261-101 – Phase 1 clinical trial of KZR-261 in patients with locally advanced or metastatic solid malignancies (ClinicalTrials.gov: NCT05047536)

- The Phase 1 clinical trial of KZR-261 is being conducted in two parts: dose escalation and dose expansion in four tumor-specific solid tumors and one all-tumor cohort. The study is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, identify a recommended Phase 2 dose and to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease.
- The KZR-261 trial is currently enrolling Cohort 7 (40 mg/m^2). Previously, Cohort 1 (1.8 mg/m^2) through Cohort 6 (27 mg/m^2) enrolled a total of 24 patients and completed rapid dose escalation without significant safety concerns.
- To date, KZR-261 has shown dose-proportional exposure and no signs of accumulation or altered pharmacokinetics with repeated dosing.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $236.6 million as of June 30, 2023, compared to $276.6 million as of December 31, 2022. The decrease was primarily attributable to cash used in operations to advance clinical-stage programs and preclinical research and development.
- **Research and development expenses** for the second quarter of 2023 increased by $9.7 million to $21.0 million compared to $11.3 million in the second quarter of 2022. This increase was primarily due to advancing the zetomipzomib clinical program in multiple indications and the KZR-261 clinical program and an increase in compensation and personnel related expenses, including non-cash stock-based compensation expense, as a result of an increase in headcount.
- **General and administrative (G&A) expenses** for the second quarter of 2023 increased by $0.8 million to $5.8 million compared to $5.0 million in the second quarter of 2022. The increase was primarily due to an increase in compensation and personnel related expenses, including non-cash stock-based compensation, as a result of an increase in headcount.
- **Net loss** for the second quarter of 2023 was $24.3 million, or $0.34 per basic and diluted common share, compared to a net loss of $16.2 million, or $0.25 per basic and diluted common share, for the second quarter of 2022.
- **Total shares of common stock outstanding** were 72.5 million shares as of June 30, 2023. Additionally, there were options to purchase 13.0 million shares of common stock at a weighted-average exercise price of $7.43 per share and 0.4 million restricted stock units outstanding as of June 30, 2023.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company discovering and developing novel 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 that has completed a Phase 2 clinical trial in lupus nephritis. 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, and follow us on LinkedIn, Facebook, Twitter and Instagram.

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" 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, initiation, progress, timing, scope and results of clinical trials, anticipated therapeutic benefit and regulatory development of 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, 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.

KEZAR LIFE SCIENCES, INC.
Selected Balance Sheets Data
(In thousands)

	June 30, 2023	December 31, 2022
	(unaudited)	

Cash, cash equivalents and marketable securities	$ 236,589	$ 276,561
Total assets	263,379	299,568
Total current liabilities	13,737	10,997
Total noncurrent liabilities	17,365	18,699
Total stockholders' equity	232,277	269,872

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended June 30		Six Months Ended June 30	
	2023	**2022**	**2023**	**2022**
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$ 20,999	$ 11,346	$ 39,317	$ 22,290
General and administrative	5,785	4,977	11,991	9,911
Total operating expenses	26,784	16,323	51,308	32,201
Loss from operations	(26,784)	(16,323)	(51,308)	(32,201)
Interest income	2,861	408	5,556	516
Interest expense	(385)	(272)	(755)	(526)
Net loss	$ (24,308)	$ (16,187)	$ (46,507)	$ (32,211)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.25)	$ (0.64)	$ (0.52)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,461,850	64,279,634	72,395,410	62,465,092

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