Kezar Life Sciences Reports Fourth Quarter and Year End 2022 Financial Results and Provides Business Update

March 14, 2023

- *PALIZADE Phase 2b clinical trial evaluating zetomipzomib in lupus nephritis to initiate in first half of 2023*
- *KZR-261 dose escalation study currently enrolling sixth cohort; the dose expansion study expected to initiate in second half of 2023*
- *Company to host a virtual Research and Development Day on March 15, 2023*
- *Cash, cash equivalents and marketable securities totaled $276.6 million as of December 31, 2022*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 14, 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 fourth quarter and year ended December 31, 2022 and provided a business update.

“We made tremendous progress in both of our first-in-class programs during 2022,” said John Fowler, Kezar’s Co-founder and Chief Executive Officer. “These successes include reporting positive Phase 2 MISSION data with zetomipzomib in lupus nephritis, selecting autoimmune hepatitis as the next indication in that program, making continued progress in our Phase 1 study with KZR-261, and presenting exciting preclinical findings from our Protein Secretion Inhibition Platform. We plan to build on this momentum in 2023, with the initiation of the PALIZADE trial in lupus nephritis patients, launching our PORTOLA trial in autoimmune hepatitis, as well as sharing topline results on the dose escalation portion of our Phase 1 study with KZR-261 in solid tumors. With our strong team and solid balance sheet, we are well positioned to deliver meaningful results across both programs in 2023 and beyond.”

Zetomipzomib: Selective Immunoproteasome Inhibitor

PALIZADE – Phase 2b clinical trial of zetomipzomib in patients with active lupus nephritis (LN)

- 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, who will be 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, and the end-of-study assessments will occur at Week 57. 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 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, randomized (2:1) to receive either 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 Phase 2 clinical trial of zetomipzomib in patients with active LN (ClinicalTrials.gov: NCT03393013)

- In November, Kezar presented positive complete results from the 37-week Phase 2 MISSION clinical trial at the American Society of Nephrology’s (ASN) Kidney Week 2022 and at the American College of Rheumatology (ACR) Convergence 2022. The posters are available to view on the Scientific Publications page of Kezar’s website.
- An abstract featuring Kezar’s post-hoc analysis across LN biopsy classes from the Phase 2 MISSION clinical trial has been selected for presentation at the upcoming National Kidney Foundation (NKF) Spring Clinical Meeting 2023, taking place April 11-15, 2023 in Austin, Texas.
- An abstract featuring Kezar’s complete MISSION Phase 1b/2 results has been selected for oral presentation at the upcoming LUPUS & KCR 2023 meeting, taking place May 17-20, 2023 in Seoul, Korea.

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. Kezar plans to initiate the dose expansion study in the second half of 2023.
- The KZR-261 trial is currently enrolling Cohort 6 (27 mg/m2). Previously, Cohort 1 (1.8 mg/m2) through Cohort 4 (12 mg/m2) enrolled a total of 12 patients and completed rapid dose escalation without significant safety concerns. Cohort 5 (18 mg/m2) enrolled six patients, and two patients are currently in the fifth cycle. The Cohort 5 dose-level is approximately equivalent to the minimally effective dose as determined in preclinical anti-tumor studies.
- To date, KZR-261 has shown dose-proportional exposure and no signs of accumulation or altered pharmacokinetics with repeated dosing. There have been no consistent patterns of safety signals. Kezar plans to report safety and dose escalation data from this trial in the second half of 2023.

KZR-540: **Selectively Blocks PD-1 Expression Via Sec61 Translocon Inhibition**

- Kezar presented promising preclinical data on KZR-540 at the Society for Immunotherapy of Cancer's (SITC) 37 th Annual Meeting in Boston, MA. KZR-540 demonstrates that the Sec61 translocon can be selectively targeted for specific anti-tumor effects and validates Sec61 inhibition as a platform for additional new chemical entities. The posters are available to view on the Scientific Publications page of Kezar's website.

Research and Development (R&D) Day Presentation

- Kezar will host a virtual R&D Day on March 15, 2023, at 4:30 pm ET/1:30 pm PT. The event will provide an extensive overview of the Company's pipeline and review the design of the PALIZADE Phase 2b clinical trial in lupus nephritis. The event will also highlight the recently announced PORTOLA Phase 2a clinical trial, including a presentation on the unmet need in autoimmune hepatitis (AIH) and the AIH treatment landscape from key opinion leader Craig S. Lammert, M.D., Assistant Professor of Medicine at Indiana University and Executive Director of the Autoimmune Hepatitis Association. Kezar will then discuss KZR-261 and developments in the Protein Secretion Platform. To register for this event, please visit the Events & Presentations page of Kezar's website.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $276.6 million as of December 31, 2022, compared to $208.4 million as of December 31, 2021. The increase was primarily attributable to net proceeds from the issuance of common stock, net of cash used in operations to advance clinical-stage programs and preclinical research and development.
- **Research and development expenses** for the fourth quarter of 2022 increased by $5.1 million to $14.9 million compared to $9.8 million in the fourth quarter of 2021. Full year R&D expenses increased by $12.1 million to $51.0 million in 2022, compared to $38.9 million in 2021. This increase was primarily due to advancing the zetomipzomib clinical program in multiple indications and the KZR-261 clinical program and an increase in stock-based compensation and personnel expenses as a result of an increase in headcount and salaries.
- **General and administrative (G&A) expenses** for the fourth quarter of 2022 increased by $0.9 million to $5.2 million compared to $4.3 million in the fourth quarter of 2021. Full year G&A expenses increased by $4.4 million to $20.1 million in 2022, compared to $15.7 million in 2021. The increase was primarily due to an increase in stock-based compensation and personnel expenses as a result of an increase in headcount and salaries.
- **Net loss** for the fourth quarter of 2022 was $18.2 million, or $0.25 per basic and diluted common share, compared to a net loss of $14.2 million, or $0.25 per basic and diluted common share, for the fourth quarter of 2021. Net loss for 2022 was $68.2 million, or $1.01 per basic and diluted common share, compared to $54.6 million, or $1.04 per basic and diluted common share, in 2021.
- **Total shares of common stock outstanding** were 68.5 million shares as of December 31, 2022. Additionally, there were outstanding pre-funded warrants to purchase 3.8 million shares of common stock at an exercise price of $0.001 per share, 0.4 million outstanding restricted stock units and options to purchase 9.7 million shares of common stock at a weighted-average exercise price of $8.12 per share as of December 31, 2022.

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.

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, the likelihood of obtaining regulatory approval of Kezar's product candidates, and our expectations to deliver meaningful results. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, the performance of audit and verification procedures, 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)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 276,561	$ 208,355
Total assets	299,568	217,933
Total current liabilities	10,997	8,212
Total noncurrent liabilities	18,699	12,845
Total stockholders' equity	269,872	196,876

Summary of Operations Data
(In thousands except share and per share data)

	Three Months Ended December 31		Year Ended December 31	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,859	$ 9,781	$ 51,009	$ 38,935
General and administrative	5,175	4,322	20,153	15,724
Total operating expenses	20,034	14,103	71,162	54,659
Loss from operations	(20,034)	(14,103)	(71,162)	(54,659)
Interest income	2,202	50	4,108	188
Interest expense	(349)	(159)	(1,185)	(159)
Net loss	$ (18,181)	$ (14,212)	$ (68,239)	$ (54,630)
Net loss per common share, basic and diluted	$ (0.25)	$ (0.25)	$ (1.01)	$ (1.04)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,231,697	55,979,764	67,368,935	52,759,335

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