Kezar Life Sciences Reports First Quarter 2024 Financial Results and Provides Business Update

May 9, 2024

- *PALIZADE Phase 2b clinical trial of zetomipzomib in patients with active lupus nephritis actively enrolling; reiterating guidance of topline data in mid-2026*
- *PORTOLA Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis actively enrolling; reiterating guidance of topline data in mid-2025*
- *KZR-261 dose expansion currently enrolling patients with melanoma; initial study data by year-end*
- *Cash, cash equivalents and marketable securities totaled $179.8 million as of March 31, 2024*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 9, 2024-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases and cancer, today reported financial results for the first quarter ended March 31, 2024 and provided a business update.

"We continued to make meaningful progress this past quarter on our mission to develop first-in-class small molecule therapeutics in immunology and oncology. We are focused this year on clinical execution in our PALIZADE and PORTOLA trials and are excited by the strong enrollment activity we have seen to date." said Chris Kirk, Kezar's Co-Founder and Chief Executive Officer. "We are also looking forward to sharing initial results from the dose escalation and dose expansion portions of the KZR-261 study in the fourth quarter of this year."

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.

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 tumor-specific solid tumors. 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 dose escalation part of the trial is completing Cohort 9 and reached a maximum tolerated dose of 80mg/m^2 based on the presence of reversible neutropenia. A total of 43 patients have been enrolled in the dose escalation part of the trial to date and additional backfill patients may be added to better understand the safety, pharmacokinetics, and pharmacodynamics of KZR-261 at specific dose levels.
- We are currently enrolling the dose expansion part of the study with a cohort of melanoma patients at a dose level of 60 mg/m^2. 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 $179.8 million as of March 31, 2024, compared to $201.4 million as of December 31, 2023. The decrease was primarily attributable to cash used in operations to advance clinical-stage programs.
- **Research and development (R&D) expenses** for the first quarter of 2024 decreased by $1.1 million to $17.2 million, compared to $18.3 million in the first quarter of 2023. This decrease was primarily due to the Company's strategic restructuring in October 2023 to prioritize its clinical-stage programs, reducing personnel-related costs and spending in its early-stage research activities. The decrease was partially offset by the increased clinical trial costs related to the PALIZADE and PORTOLA trials, as well as manufacturing expenses.
- **General and administrative (G&A) expenses** for the first quarter of 2024 increased by $0.3 million to $6.5 million compared to $6.2 million in the first quarter of 2023. The increase was primarily due to an increase in non-cash stock-based compensation and personnel-related expenses, offset by a decrease in legal and professional service expenses.
- **Net loss** for the first quarter of 2024 was $21.7 million, or $0.30 per basic and diluted common share, compared to a net loss of $22.2 million, or $0.31 per basic and diluted common share, for the first quarter of 2023.
- **Total shares of common stock outstanding** were 72.8 million shares as of March 31, 2024. Additionally, there were options to purchase 15.6 million shares of common stock at a weighted-average exercise price of $2.27 per share and 0.2 million restricted stock units outstanding as of March 31, 2024.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases and cancer. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated in a Phase 2b clinical trial for lupus nephritis and a Phase 2a clinical trial for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. Kezar's oncology product candidate, KZR-261, targeting the Sec61 translocon and protein secretion pathway, is being evaluated in an open-label Phase 1 clinical trial to assess safety, tolerability and preliminary tumor activity in solid tumors. 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," "anticipate" 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, the enrollment and expected timing of reporting topline data from our clinical trials, the development of zetomipzomib in additional indications, 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 clinical trial site activation or enrollment rates that are lower than expected, 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)

	March 31, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 179,798	$ 201,372
Total assets	199,130	221,235
Total current liabilities	16,161	17,744
Total noncurrent liabilities	13,848	15,921
Total stockholders' equity	169,121	187,570

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

	Three Months Ended March 31	
	2024	2023

	(unaudited)	
Operating expenses:		
Research and development	$ 17,172	$ 18,318
General and administrative	6,539	6,206
Total operating expenses	23,711	24,524
Loss from operations	(23,711)	(24,524)
Interest income	2,453	2,695
Interest expense	(400)	(370)
Net loss	$ (21,658)	$ (22,199)
Net loss per common share, basic and diluted	$ (0.30)	$ (0.31)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,799,910	72,328,231

View source version on businesswire.com: https://www.businesswire.com/news/home/20240509839405/en/

Investor and Media Contact:
Gitanjali Jain
Vice President, Investor Relations and External Affairs
Kezar Life Sciences, Inc.
gjain@kezarbio.com

Source: Kezar Life Sciences, Inc.