Kezar Life Sciences Reports Third Quarter 2022 Financial Results and Provides Business Update

November 10, 2022

- *Presented positive complete results from the MISSION Phase 2 trial evaluating zetomipzomib in patients with lupus nephritis at ASN's Kidney Week 2022 Annual Meeting*
- *Received FDA clearance of IND for zetomipzomib for the treatment of autoimmune hepatitis*
- *Cash, cash equivalents and marketable securities totaled $290.4 million as of September 30, 2022*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 10, 2022-- 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 third quarter ended September 30, 2022 and provided a business update.

"In the third quarter, the team at Kezar continued its tradition of strong execution across our clinical and portfolio development plans," said John Fowler, Kezar's Co-founder and Chief Executive Officer. "Supported by the results from the MISSION study, our conviction remains high that zetomipzomib has the potential to be a non-immunosuppressive, steroid-sparing treatment for patients with lupus and lupus nephritis. In addition, our recently announced development plan in autoimmune hepatitis underscores our belief that zetomipzomib can help patients across a diverse range of autoimmune diseases. In parallel, we are excited by progress in our protein secretion inhibition platform and look forward to our SITC poster presentation tomorrow on KZR-540, an oral small molecule that selectively blocks PD-1 expression."

Zetomipzomib: Selective Immunoproteasome Inhibitor

MISSION – Phase 2 clinical trial of zetomipzomib in patients with active lupus nephritis (LN) (NCT03393013)

- Kezar presented positive complete results for the 37-week Phase 2 MISSION clinical trial at the American Society of Nephrology's (ASN) Kidney Week 2022 Annual Meeting.
  - During the 24-week treatment period, patients received 60 mg of zetomipzomib subcutaneously once weekly (first dose of 30 mg) in addition to stable background therapy. End-of-treatment assessments occurred at Week 25 (EOT), with a safety follow up period and completion of the study at Week 37 (EOS). Patients in the MISSION Phase 2 clinical trial received zetomipzomib without induction therapy, which represents a difference from other recently published clinical trials in LN. The primary efficacy endpoint for the trial was the proportion of patients achieving an overall renal response (ORR), measured as a 50% or greater reduction in urine protein to creatinine ratio (UPCR) at end-of-treatment. A key secondary efficacy endpoint was the number of patients with a complete renal response (CRR), measured as an absolute reduction in proteinuria values to a UPCR of 0.5 or less, with preserved renal function (eGFR), and corticosteroid use of 10 mg or less prednisone/prednisone equivalent and no use of prohibited medication.
- In the MISSION Phase 2 clinical trial, 17 of 21 enrolled patients reached end-of-treatment at Week 25 and end-of-study at Week 37:
  - ORRs were achieved in 11 of 17 patients (64.7%) at EOT. This benefit occurred with a 53% mean reduction of background corticosteroid use.
  - During the safety follow up period, clinical responses deepened, and ORRs increased to 16 patients (94.1%) at Week 29 and 15 patients (88.2%) at EOS. Of these responders, 12 patients (70.6%) also reached a UPCR of 0.7 or less at EOS.
  - CRRs were achieved in 6 of 17 patients (35.3%) at EOT, including a UPCR of 0.5 or less, stable eGFR, daily prednisone/prednisone equivalent dose of 10 mg or less, and no use of prohibited medication.
  - During the safety follow up period, an additional patient achieved a CRR, with the total CRRs increasing to 7 patients (41.2%) at both Week 29 and EOS.
  - Key measurements of SLE disease activity were reduced and key biomarkers of SLE improved. There was no evidence of early rebound of inflammation following discontinuation of zetomipzomib.
- Kezar will also present the complete MISSION data set at the upcoming American College of Rheumatology (ACR) Convergence 2022, which is taking place November 10 – 14, 2022 in Philadelphia, PA. The ACR poster presentation details are available here.

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

- In October 2022, Kezar received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration for zetomipzomib for the treatment of AIH. AIH is a rare, chronic disease in which the immune system

attacks the liver and causes inflammation and tissue damage, severely impacting patients' physical health and quality of life.
- The PORTOLA trial (KZR-616-208) 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, who will be randomly assigned (2:1) to receive either zetomipzomib or placebo in addition to background corticosteroid therapy for 24 weeks and includes 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.

Protein Secretion Inhibition

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

- KZR-261 is a novel, broad-spectrum agent that acts through direct interaction and inhibition of the Sec61 translocon. In preclinical studies, KZR-261 has been shown to induce a direct anti-tumor effect as well as modulate the tumor microenvironment, including enhancing anti-tumor immune responses.
- The Phase 1 clinical trial of KZR-261 is being conducted in two parts: dose escalation, and dose expansion in subjects with selected tumor types. The trial is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well as to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease.

KZR-540 – Kezar will introduce promising preclinical data on KZR-540, an oral small molecule inhibitor that selectively blocks PD-1 expression via inhibition of the Sec61 translocon, on November 11, 2022 at the Society for Immunotherapy of Cancer's (SITC) 37 th Annual Meeting in Boston, MA. KZR-540 illustrates that the Sec61 translocon can be selectively inhibited for specific anti-tumor effects and validates Sec61 inhibition as a platform for additional new chemical entities.

- Details for the SITC poster presentation are as follows:
  - **Title:** KZR-540 is a novel oral small molecule inhibitor of Sec61 cotranslational translocation that potently and selectively blocks PD-1 expression (#422)
  - **Category:** Checkpoint Blockade Therapy
  - **Date/Time:** November 11, 2022 from 9 AM – 8:30 PM ET
  - **Presenter:** Cristina Delgado-Martin, Senior Scientist, Biology

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $290.4 million as of September 30, 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 under the "at-the-market" Sales Agreement with Cowen and Company, LLC, net of cash used in operations to advance clinical-stage programs and preclinical research and development.
- **Research and development expenses** for the third quarter of 2022 increased by $3.4 million to $13.9 million compared to $10.5 million in the third quarter of 2021. This increase was primarily due to an increase in personnel-related expenses including non-cash stock-based compensation because of headcount growth, and higher research and clinical development expenses, to advance the zetomipzomib clinical programs and the KZR-261 Phase 1 clinical trial.
- **General and administrative expenses** for the third quarter of 2022 increased by $1.0 million to $5.0 million compared to $4.0 million in the third quarter of 2021. The increase was primarily due to an increase in personnel-related expenses including non-cash stock-based compensation.
- **Net loss** for the third quarter of 2022 was $17.8 million, or $0.25 per basic and diluted common share, compared to a net loss of $14.5 million, or $0.28 per basic and diluted common share, for the third quarter of 2021.
- **Total shares of common stock outstanding** were 68.4 million shares as of September 30, 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 9.6 million shares of common stock at a weighted-average exercise price of $8.12 per share as of September 30, 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 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, 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, 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)

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and marketable securities	$290,383	$208,355
Total assets	304,770	217,933
Total current liabilities	9,595	8,212
Total noncurrent liabilities	11,987	12,845
Total stockholders' equity	283,188	196,876

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$13,860	$10,527	$36,150	$29,154
General and administrative	5,067	3,972	14,978	11,402
Total operating expenses	18,927	14,499	51,128	40,556
Loss from operations	(18,927)	(14,499)	(51,128)	(40,556)
Interest income	1,390	37	1,906	138
Interest expense	(310)	—	(836)	—
Net loss	($17,847)	($14,462)	($50,058)	($40,418)
Net loss per common share, basic and diluted	($0.25)	($0.28)	($0.76)	($0.78)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,153,952	52,048,563	65,730,202	51,674,063

View source version on businesswire.com: https://www.businesswire.com/news/home/20221110005886/en/

Investor:
Gitanjali Jain
Vice President, Investor Relations and External Affairs
gjain@kezarbio.com

Media:
Julia Deutsch
Solebury Strategic Communications
jdeutsch@soleburystrat.com

Source: Kezar Life Sciences, Inc.