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

August 11, 2022

- *Announced positive topline results from the MISSION Phase 2 Trial evaluating zetomipzomib for the treatment of patients with lupus nephritis*
- *Appointed Nick Mordwinkin, Pharm.D., Ph.D. as Chief Business Officer*
- *Cash, cash equivalents and marketable securities totaled $306.8 million as of June 30, 2022*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 11, 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 second quarter ended June 30, 2022 and provided a business update.

"The second quarter was tremendously productive for Kezar, during which we achieved key clinical milestones, strengthened our balance sheet, and added great talent to our leadership team, marking a major step in our growth," said John Fowler, Kezar's Co-founder and Chief Executive Officer. "We shared exciting positive topline results from our MISSION Phase 2 study evaluating zetomipzomib in LN patients, and our Phase 1 trial in solid tumors with our novel protein secretion inhibitor, KZR-261 is progressing as planned. We look forward to continued momentum across the company for the rest of 2022 and providing further updates in the coming months."

Zetomipzomib: Selective Immunoproteasome Inhibitor

MISSION – Phase 1b/2 clinical trial of zetomipzomib (KZR-616) in patients with systemic lupus erythematosus with and without active lupus nephritis (LN) (NCT03393013)

- In June 2022, Kezar reported topline results from the open-label MISSION Phase 2 clinical trial evaluating zetomipzomib in patients with active LN.
    - 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, with completion of study at Week 37. Patients in the MISSION Phase 2 clinical trial received zetomipzomib without induction therapy, which represents a difference from other recently published 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 Phase 2 topline analysis, 17 of 21 patients enrolled in the trial reached end of treatment:
    - 11 of 17 patients (64.7%) achieved an ORR measured as a 50% or greater reduction in UPCR at end of treatment compared to baseline, the primary efficacy endpoint of the clinical trial.
    - 6 of 17 patients (35.2%) achieved a CRR of 0.5 UPCR or less, with all other protocol definitions satisfied.
    - Treatment benefit of zetomipzomib was maintained or deepened following the end of treatment, based on assessments at Week 29.
        - 16 of 17 patients (94.1%) reached an ORR at Week 29, and 6 patients maintained a CRR.
    - Patients' mean daily prednisone background dosage was reduced from 19.2 mg at baseline to 9.1 mg at week 25 and was further reduced at Week 29.
- Also in June, Kezar presented a poster featuring zetomipzomib as part of the EULAR Science Exhibit session at the Annual European Congress of Rheumatology (EULAR) in Copenhagen, Denmark.
    - *POS0715: Treatment of SLE Patients with Zetomipzomib (KZR-616), a Selective Inhibitor of the Immunoproteasome, Results in Circulating Gene Expression, Protein Level, and Immune Cell Phenotypic Changes with Potential Correlations to Clinical Response,* presented by Andrea Fan, Ph.D., Vice President, Head of Biology and Translational Research, Kezar Life Sciences.

KZR-261: Protein Secretion Inhibitor

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.
- At the American Association of Cancer Research (AACR) 2022 Annual Meeting, held in April 2022 in New Orleans, LA, Kezar presented data on its proprietary small molecule inhibitors of the Sec61 translocon, specifically KZR-834, a working analog of KZR-261.

Appointment of Chief Business Officer

- In July 2022, Nick Mordwinkin, Pharm.D., Ph.D., was appointed as Chief Business Officer. Dr. Mordwinkin brings over a decade of experience in leadership, corporate development and strategic partnership roles in the healthcare industry. Dr. Mordwinkin will be responsible for shaping and overseeing the Company's business development strategy.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $306.8 million as of June 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 by the company in operations to advance its clinical-stage programs and preclinical research and development.
- **Research and development expenses** for the second quarter of 2022 increased by $2.0 million to $11.3 million compared to $9.3 million in the second quarter of 2021. This increase was primarily related to advancing the zetomipzomib clinical programs and the KZR-261 Phase 1 clinical trial.
- **General and administrative expenses** for the second quarter of 2022 increased by $1.3 million to $5.0 million compared to $3.7 million in the second quarter of 2021. The increase was primarily due to an increase in personnel expenses, including non-cash stock-based compensation and an increase in professional services.
- **Net loss** for the second quarter of 2022 was $16.2 million, or $0.25 per basic and diluted common share, compared to a net loss of $13.0 million, or $0.25 per basic and diluted common share, for the second quarter of 2021.
- **Total shares of common stock outstanding** were 68.3 million shares as of June 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 and outstanding options to purchase 9.2 million shares of common stock at a weighted-average exercise price of $8.05 per share as of June 30, 2022.

About Zetomipzomib (KZR-616)

Zetomipzomib (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 1 clinical trials provide evidence that zetomipzomib exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases.

About Lupus Nephritis

Lupus nephritis (LN) is one of the most serious complications of systemic lupus erythematosus (SLE). LN is a disease comprising a spectrum of vascular, glomerular and tubulointerstitial lesions and develops in approximately 50% of SLE patients within 10 years of their initial diagnosis. LN is associated with considerable morbidity, including an increased risk of end-stage renal disease requiring dialysis or renal transplantation and an increased risk of death. There are limited approved therapies for the treatment of LN. Management typically consists of induction therapy to achieve remission and long-term maintenance therapy to prevent relapse.

About KZR-261 and the Inhibition of Protein Secretion

KZR-261 is a first-in-class small molecule compound, derived from Kezar's research and discovery platform of protein secretion pathway inhibitors. This broad-spectrum anti-tumor agent directly targets the Sec61 translocon and inhibits multiple cancer drivers both within tumor cells and the tumor microenvironment. A Phase 1 clinical trial is underway for the treatment of solid tumor malignancies.

Kezar's drug discovery platform of protein secretion pathway inhibitors is a novel approach with broad application. The protein secretion pathway is a highly conserved and ubiquitously functioning pathway in all cells in the body and involves a conserved protein complex called the Sec61 translocon, the target of Kezar's compounds. In preclinical models, Kezar's library of protein secretion inhibitors have demonstrated broad activity with far-reaching potential in oncology, immune-oncology, and autoimmunity.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company discovering and developing 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 to inhibit multiple drivers of disease via single, powerful targets. Zetomipzomib, its lead development asset, is a selective immunoproteasome inhibitor being evaluated in 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," "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 design, progress, timing, scope and results of clinical trials, anticipated regulatory development of Kezar's product candidates, the preliminary nature of topline data, 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 the performance of audit and verification procedures on topline data, delays in cleaning and verifying clinical trial data, unexpected safety or efficacy data observed during clinical studies, the impacts of the COVID-19 pandemic and other global events on the company's business and 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, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and marketable securities	$306,838	$208,355
Total assets	317,502	217,933
Total current liabilities	7,853	8,212
Total noncurrent liabilities	12,285	12,845
Total stockholders' equity	297,364	196,876

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

	Three Months Ended June 30		Six Months Ended June 30	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$11,346	$9,341	$22,290	$18,627
General and administrative	4,977	3,668	9,911	7,430
Total operating expenses	16,323	13,009	32,201	26,057
Loss from operations	(16,323)	(13,009)	(32,201)	(26,057)
Interest income	408	47	516	101
Interest expense	(272)	—	(526)	—
Net loss	($16,187)	($12,962)	($32,211)	($25,956)
Net loss per common share, basic and diluted	($0.25)	($0.25)	($0.52)	($0.50)
Weighted-average shares used to compute net loss per common share, basic and diluted	64,279,634	51,904,701	62,465,092	51,483,709

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