

# Kezar Life Sciences Reports Third Quarter 2019 Financial Results and Provides Business Update

- *Additional data from the ongoing Phase 1b portion of the MISSION study to be presented at the 2019 ACR/ARP Meeting in Atlanta, GA*
- *Phase 2 MISSION, PRESIDIO, and MARINA trials with KZR-616 are progressing*
- *KZR-261 nominated as the first oncology clinical candidate from the Protein Secretion Program*
- *Protein Secretion Program to be featured in oral and poster presentations at SITC and ASH*

SAN FRANCISCO, Nov. 06, 2019 (GLOBE NEWSWIRE) -- Kezar Life Sciences, Inc. (Nasdaq: [KZR](#)), a clinical-stage biotechnology company discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer, today announced its third quarter 2019 financial results and corporate highlights.

“I commend our team’s continued execution across our clinical and preclinical programs here at Kezar. Our three Phase 2 trials with KZR-616 in severe autoimmune diseases are progressing on track, and we look forward to disclosing additional data from our MISSION study at the ACR meeting next week”, said John Fowler, Chief Executive Officer.

“Additionally, the nomination of the first clinical candidate from our protein secretion program is a pivotal step for the company and underscores the depth and breadth of our R&D capabilities. Our small molecule approach to targeting the Sec61 translocon represents a highly compelling new therapeutic approach, and the preclinical data generated with KZR-261 gives us confidence that it may prove effective in treating a variety of tumor types. We are excited to share more about this highly novel target and illustrate the broad platform potential of this approach.”

## Recent Clinical and Business Highlights

### **KZR-616 – Selective Immunoproteasome Inhibitor**

#### ***MISSION Study***

The Phase 1b/2 MISSION study in systemic lupus erythematosus (SLE) patients with and without nephritis is currently ongoing.

- On October 1, 2019, we presented a corporate and strategic update, including a protocol amendment for the Phase 2 portion of the MISSION study ([NCT03393013](#)). The updated protocol is designed to generate more robust and meaningful data around the safety and efficacy of KZR-616 in lupus nephritis, including the evaluation of three dose levels of KZR-616 (administered with background medication) for a treatment period of six months.
- The Phase 1b portion of the MISSION study is ongoing and additional data will be

presented during a poster session at the 2019 American College of Rheumatology (ACR) Meeting in Atlanta, GA on November 12, 2019.

### **PRESIDIO Study**

In August 2019, we announced the initiation of the PRESIDIO study ([NCT04033926](#)), a Phase 2 randomized, double-blind, placebo-controlled, crossover, multicenter study to evaluate the safety, tolerability, efficacy, PK and PD of treatment with KZR-616 in patients with active dermatomyositis (DM) or polymyositis (PM). This trial is expected to enroll 24 patients with either DM or PM.

### **MARINA Study**

In August 2019, we announced the initiation of the MARINA study ([NCT04039477](#)), a Phase 2 randomized, dose-blind, multicenter study to evaluate the safety and efficacy of KZR-616 in the treatment of patients with autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP). This trial is expected to enroll 40 patients with either AIHA or ITP.

### **KZR-261 – Protein Secretion Program**

- Our research and discovery efforts targeting the protein secretion pathway have progressed significantly, and today, we announce the nomination of KZR-261 as our first oncology clinical candidate. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies, and we have initiated laboratory studies and manufacturing activities towards an Investigational New Drug (IND) filing for a Phase 1 study in solid tumors, which we anticipate occurring in Q1 2021.
- Additionally, this novel program and pathway will be featured in four separate presentations during two major medical and scientific conferences: the Society for Immunotherapy of Cancer (SITC) and the 61<sup>st</sup> American Society of Hematology Meeting & Exposition (ASH). The abstract titles are summarized below.

**SITC:** November 6-10, 2019, National Harbor, MD

- Abstract Number: 815  
Title: [Targeting multiple immune checkpoint proteins with novel small molecule inhibitors of Sec61-dependent cotranslational translocation](#)  
Date: Friday, November 8, 2019  
Time: 12:30pm – 2:00pm  
Poster Session: Novel Single-Agent Immunotherapies

**ASH:** December 7-10, 2019, Orlando, FL

*Oral Presentations*

- Abstract Number: 408  
Title: [Blocking Protein Secretion with Novel Small Molecule Inhibitors of Sec61 Represents a Potential Treatment Strategy Against Hematologic Malignancies](#)  
Date: Sunday, December 8, 2019  
Time: 10:45am  
Oral Session: 802. Chemical Biology and Experimental Therapeutics: Novel Compounds and Mechanisms of Action

- Abstract Number: 805  
Title: [Protein Translocation Inhibitors Overcome Cytokine-Induced Glucocorticoid Resistance in T-Cell Acute Lymphoblastic Leukemia](#)  
Date: Monday, December 9, 2019  
Time: 4:30 PM  
Oral Session: 605. Molecular Pharmacology, Drug Resistance—Lymphoid and Other

#### *Poster Presentation*

- Abstract Number: 2076  
Title: [Proteomic Profiling and Mechanistic Investigating of a Novel Anti-Cancer Small Molecule Inhibitor of Sec61](#)  
Date: Saturday, December 7, 2019  
Time: 5:30 PM - 7:30 PM  
Poster Session: 802. Chemical Biology and Experimental Therapeutics: Poster I

#### **Financial Results**

- **Cash, cash equivalents and marketable securities** totaled \$85.2 million as of September 30, 2019, compared to \$107.4 million as of December 31, 2018. The decrease in cash, cash equivalents and marketable securities was primarily attributable to cash used by the company in operations to advance its clinical stage programs as well as preclinical research and development.
- **Research and development expenses** for the third quarter of 2019 increased by \$2.4 million to \$7.1 million compared to \$4.7 million in the third quarter of 2018. This increase was primarily related to advancing both the KZR-616 clinical program in multiple indications and the protein secretion preclinical program.
- **General and administrative expenses** for the third quarter of 2019 increased by \$1.0 million to \$2.6 million compared to \$1.6 million in the third quarter of 2018. The increase was primarily due to an increase in personnel expenses and costs related to operating as a public company.
- **Net loss** for the third quarter of 2019 was \$9.1 million, or \$0.48 per basic and diluted common share, compared to a net loss of \$5.7 million, or \$0.30 per basic and diluted common share, for the third quarter of 2018.
- **Total shares outstanding** were 19.1 million as of September 30, 2019. Additionally, there were outstanding options to purchase 3.3 million shares of common stock at a weighted average exercise price of \$7.39 per share as of September 30, 2019.

#### **About KZR-616**

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. Phase 1a clinical trial results in healthy volunteers provide evidence

that KZR-616 potentially avoids adverse effects caused by currently marketed non-selective proteasome inhibitors, which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. Phase 2 trials are underway for the treatment of lupus nephritis (MISSION study), dermatomyositis and polymyositis (PRESIDIO study), and autoimmune hemolytic anemia and immune thrombocytopenia (MARINA study).

### **About KZR-261**

KZR-261, a novel, first-in-class protein secretion inhibitor, is the first clinical candidate to be nominated from our research and discovery efforts targeting protein secretion pathways as potential therapies for oncology, immuno-oncology and autoimmune indications. KZR-261 is a broad-spectrum anti-tumor agent that acts through direct interaction and inhibition of Sec61 activity. The compound was discovered at Kezar through a medicinal chemistry campaign in which several scaffolds were progressed through the company's proprietary work flow of Sec61 modulation. As a result, Kezar has established a unique and broad library of protein secretion inhibitors and a strong patent position around KZR-261 and its analogs. KZR-261 has demonstrated several encouraging features that lend to its potential to be a new anti-cancer agent for the treatment of solid and hematologic malignancies. IND-enabling studies are currently underway, and an IND filing in solid tumors is expected in Q1 2021.

### **About Kezar Life Sciences**

Based in South San Francisco, Kezar Life Sciences is a clinical-stage biotechnology company committed to revolutionizing treatments for patients with autoimmune diseases and cancer. Kezar is translating its innovative research on the immunoproteasome and protein secretion pathways to advance novel therapeutic approaches. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe and underserved autoimmune diseases. Additionally, Kezar has nominated KZR-261 as its first clinical candidate for the treatment of cancer from its protein secretion program and will now enter into IND-enabling studies for the program. For more information, visit [www.kezarlifesciences.com](http://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, the anticipated timing of disclosure of results of clinical trials, the likelihood data will support future development, the association of data with treatment outcomes, the likelihood of obtaining regulatory approval of Kezar's product candidates, and the discovery and development of new product candidates. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data

observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, 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.

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**KEZAR LIFE SCIENCES, INC.**

**Selected Balance Sheets Data**

(In thousands)

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 85,243	\$ 107,432
Total assets	97,523	114,682
Total current liabilities	5,327	3,337
Total stockholders' equity	86,497	108,797

**KEZAR LIFE SCIENCES, INC.**

**Condensed Consolidated  
Statements of Operations**

(In thousands except share and per share data)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$ 7,080	\$ 4,664	\$ 19,932	\$ 13,463
General and administrative	2,601	1,600	7,413	4,837
Total operating expenses	9,681	6,264	27,345	18,300
Loss from operations	(9,681)	(6,264)	(27,345)	(18,300)
Interest income	533	601	1,837	915
Net loss	(\$ 9,148)	(\$ 5,663)	(\$ 25,508)	(\$ 17,385)
Net loss per common share, basic and diluted	(\$ 0.48)	(\$ 0.30)	(\$ 1.34)	(\$ 2.38)

Weighted-average shares used to  
compute net loss per common share,  
basic and diluted

19,095,870	18,955,384	19,070,937	7,319,012
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Source: Kezar Life Sciences, Inc.