

October 27, 2021



Kezar Announces First Patient Dosed in Phase 1 Trial of KZR-261 in Advanced Solid Tumor Malignancies

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--[Kezar Life Sciences, Inc.](#) (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today announced that the first patient has been dosed in KZR-261-101, a Phase 1 clinical trial evaluating KZR-261, a novel, broad-spectrum, anti-tumor agent that acts through direct interaction and inhibition of the Sec61 translocon.

“Dosing the first patient with KZR-261, the first clinical candidate from our novel protein secretion platform, is an exciting milestone for Kezar as we continue to advance our oncology program and mature into a multi-asset therapeutics company,” said John Fowler, Co-Founder and Chief Executive Officer of Kezar Life Sciences. “We believe KZR-261 has a differentiated therapeutic profile which could translate into broad potential across the oncology landscape.”

KZR-261-101 is a first-in-human, open-label, multicenter, Phase 1 study of KZR-261 in patients with solid tumor malignancies. The study is being conducted in two parts, dose escalation and dose expansion, and is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well as to explore the preliminary anti-tumor activity of KZR-261 in subjects with locally advanced or metastatic disease for whom no therapeutics are currently available. Following safety review of all dose escalation cohorts and determination of the maximum tolerated dose or maximum administered dose, KZR-261 will be evaluated for safety and preliminary efficacy in four tumor-specific cohorts and one all-tumor cohort to determine doses recommended for Phase 2 studies.

Additional information about the KZR-261-101 trial is available via [Clinicaltrials.gov](#) (NCT 05047536).

About KZR-261

KZR-261, a novel, first-in-class protein secretion inhibitor, is the first clinical candidate to be nominated from Kezar’s research and discovery efforts targeting the protein secretion pathway. KZR-261 is a broad-spectrum anti-tumor agent that acts through direct interaction and inhibition of Sec61 activity. The compound was discovered by Kezar through a robust medicinal chemistry campaign in which several scaffolds were progressed through the company’s proprietary platform evaluating Sec61 modulation. KZR-261 has demonstrated several encouraging properties that lead to its potential to be an anti-cancer agent, and a Phase 1 trial is underway for the treatment of solid tumor malignancies.

About Inhibition of Protein Secretion

In mammalian cells, the secretion of proteins such as cytokines and growth factors and the expression of cell surface transmembrane proteins such as receptor tyrosine kinases and immune checkpoint molecules involve a process called cotranslational translocation. For most proteins, this process occurs via the Sec61 translocon, a highly conserved multi-subunit protein complex found in the membrane of the endoplasmic reticulum of all cells. Kezar scientists have been researching the protein secretion pathway and ways to drug this important cellular pathway for more than five years and developed novel and robust assays to discover and develop small molecule inhibitors of Sec61. As a result, Kezar has established a broad library of protein secretion inhibitors for potential development across a wide range of diseases.

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. KZR-616, its lead development candidate, is a selective immunoproteasome inhibitor being evaluated in Phase 2 clinical trials in lupus nephritis, dermatomyositis and polymyositis. Additionally, 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, the anticipated timing of disclosure of results of clinical trials and the anticipated regulatory development of Kezar's product candidates. Many factors may cause differences between current expectations and actual results, including the impacts of the COVID-19 pandemic on the company's business, clinical trials and financial position, 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20211027005336/en/>

Gitanjali Jain

Vice President, Investor Relations and External Affairs

650-269-7523

gjain@kezarbio.com

Kimberly Minarovich

Argot Partners

212-600-1902

kezar@argotpartners.com

Source: Kezar Life Sciences, Inc.