UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 3, 2019

KEZAR LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38542**	**47-3366145**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4000 Shoreline Court, Suite 300	
South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 822-5600

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	KZR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure

On October 3, 2019, John Fowler, the Chief Executive Officer of Kezar Life Sciences, Inc. (the "Company"), presented a corporate and strategic update at the 2019 Cantor Global Healthcare Conference in New York, NY. A copy of the slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information provided in Item 7.01 of this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Slide Presentation, dated October 3, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KEZAR LIFE SCIENCES, INC.

By: /s/ Marc L. Belsky
Marc L. Belsky
Chief Financial Officer and Secretary

Dated: October 3, 2019

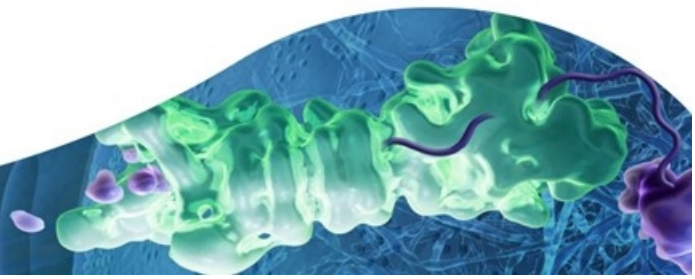
Exhibit 99.1

KEZAR LIFE SCIENCES

Revolutionizing the Treatment of Autoimmune Disorders and Malignancies

Investor Presentation

October 2019



Forward-Looking Statements Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “target,” and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. Each of these forward-looking statements involves substantial risks and uncertainties that could cause actual results to differ significantly from those expressed or implied by such forward-looking statements. Forward-looking statements contained in this presentation include, but are not limited to, statements regarding the potential use of our product candidates to treat patients, the association of data with treatment outcomes, the design, timing of initiation, progress, enrollment and scope of clinical trials for our product candidates, the expected timing of program updates and data disclosures, the timing of filing INDs and other regulatory documents, the timing and likelihood of seeking regulatory approval for our product candidates, and the patient prevalence, regulatory pathway and competitive landscape for our product candidates.

These forward-looking statements reflect Kezar's current beliefs and expectations. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, and unexpected litigation or other disputes. Other factors that may cause our actual results to differ from current expectations are discussed in Kezar’s most recent Form 10-K or Form 10-Q filed with the U.S. Securities and Exchange Commission, under the caption “Risk Factors” and elsewhere in such reports. Except as required by law, we assume 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

The Kezar Opportunity: Pioneering immunoproteasome inhibition, a new approach in autoimmunity

KZR-616: A Novel, Differentiated Approach	• Potential to be a first-in-class selective immunoproteasome inhibitor • Uniquely broad immunomodulatory approach, with target expressed across all immune cell types • Potential to bring clinical benefit without immunosuppression • Builds on strong clinical data with non-selective proteasome inhibitors
Rich Platforms & Growing Pipeline	• KZR-616 is a pipeline in a drug, targeting a wide range of unmet needs in both rare and large market autoimmune indications • Protein secretion platform offers significant potential to generate novel drugs; 1st oncology clinical candidate nomination by YE 2019
Strong Clinical and Safety Data w/KZR-616	• Phase 1b in SLE patients shows favorable safety profile over nonselective proteasome inhibitors • Clinical activity seen across multiple disease parameters • Consistent pharmacology seen across three clinical trials
Value Drivers in Multiple Indications	• Phase 2 trial in LN recruiting; initial Phase 1b data presented at EULAR 2019; additional data in Q4 2019 • Trials in DM and PM, AIHA and ITP open for enrollment
Strong Cash Position	• Cash, cash equivalents, and marketable securities: $93.4M (as of 6/30/19)

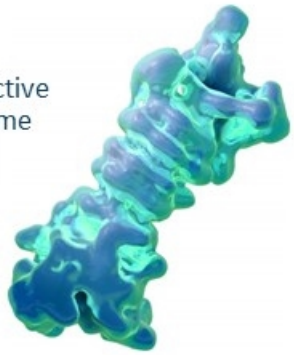
KZR-616 and our Protein Secretion Program will address a diverse pipeline of indications

Program	Therapeutic Indication	Development Stage			
		Discovery	Preclinical	Phase 1	Phase 2
KZR-616	Lupus Nephritis (LN)	*MISSION – Phase 2*			
	Dermatomyositis (DM) Polymyositis (PM)	*PRESIDIO – Phase 2*			
	Autoimmune Hemolytic Anemia (AIHA) Immune Thrombocytopenia (ITP)	*MARINA – Phase 2*			
Protein Secretion	Oncology	Clinical Candidate in Q4			
	Oncology & Autoimmunity				

Kezar's novel, complementary drug discovery and development programs target protein homeostasis

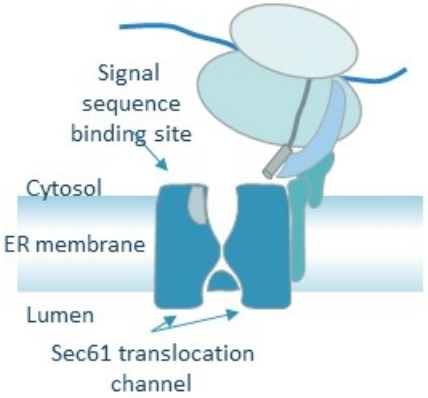
Protein Degradation: The Immunoproteasome

The target of selective immunoproteasome inhibitor KZR-616



- Modulates multiple drivers of inflammation
- Restores normal immune responses in autoimmune disorders, while avoiding immunosuppression
- Active in broad array of autoimmune disease models

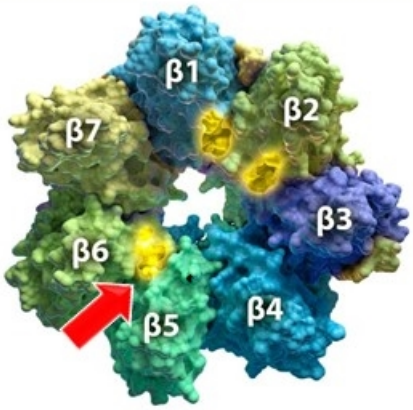
Protein Secretion: The Sec61 Translocon



- Broad anti-tumor activity in preclinical models
- Applications in oncology, immuno-oncology, and autoimmunity

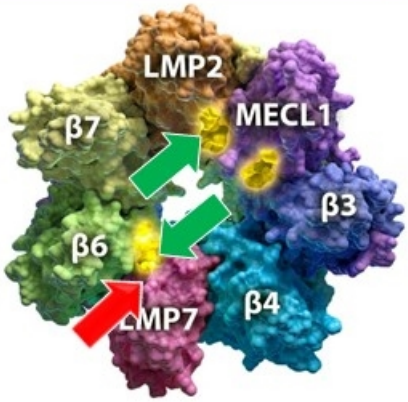
The immunoproteasome is a unique type of proteasome expressed only in the immune system and at sites of inflammation

Constitutive proteasome



Ubiquitous Expression
(e.g. heart and liver)

Immunoproteasome



Expressed in Immune System
(e.g. T-cells)

Primary targets of approved drugs VELCADE and KYPROLIS

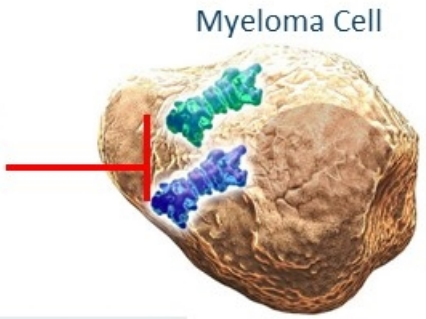
Primary targets of KZR-616

*Active sites inducing protein degradation are highlighted

Groettrup, Kirk, and Basler Nat Rev Immunol 2010

Selective inhibition of the immunoproteasome is not cytotoxic and results in broad immunomodulatory activity

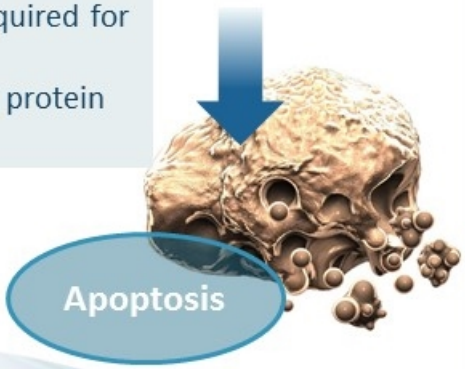
Dual-Targeting Proteasome Inhibitors



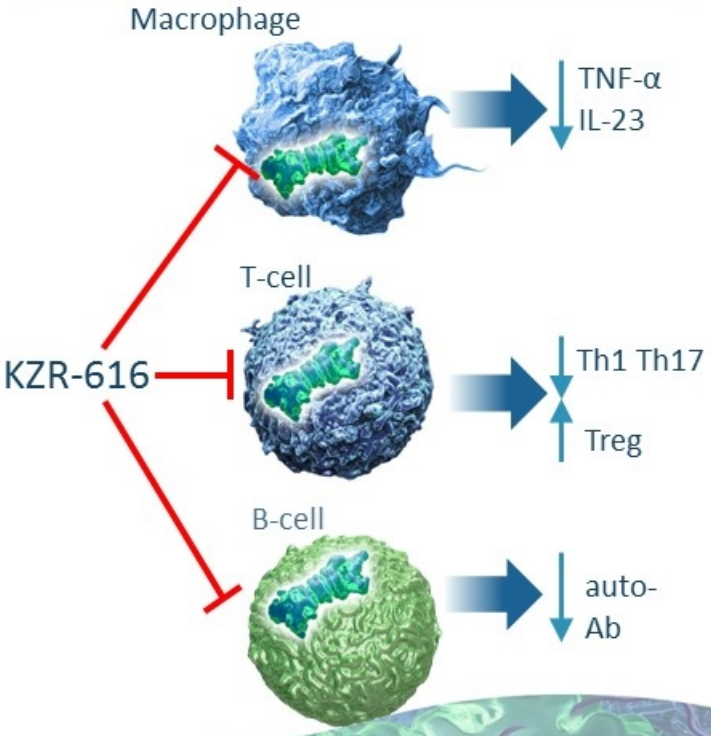
VELCADE (bortezomib)

KYPROLIS (carfilzomib)

- Dual inhibition required for cell death
- Death induced by protein buildup (UPR)



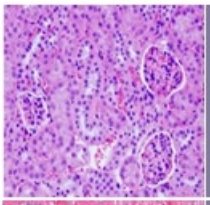
Selective Immunoproteasome Inhibitors



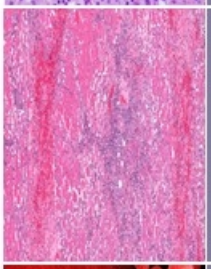
Parlati et al. Blood 2009

KEZAR LIFE SCIENCES

KZR-616 has the potential to address significant unmet needs in severe autoimmune diseases



Lupus Nephritis (LN)
Prevalence: *~150K US patients*
Treatment: *No approved treatments in US/EU*



Dermatomyositis (DM)/ Polymyositis (PM)
Prevalence: ~70K US patients
Treatment: *No approved treatments in US/EU*

Autoimmune Hemolytic Anemia (AIHA)/Immune Thrombocytopenia (ITP)
Prevalence: ~140K US patients
Treatment: *No approved treatments for AIHA in US/EU; limited available treatments for ITP*

Prolonged corticosteroid use results in significant complications

Existing therapies are ineffective in many patients

Targeted therapies (e.g. biologics) may not address needs of all patients with diseases characterized by defects in multiple arms of the immune system

Almani S et al. CJASN 2017
Oddis C et al. Nat Rev Rheumatol 2018
Barcellini W et al. Expert Rev Clin Immunol 2018
Lambert MP et al. Blood 2017
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4386579/figure/Fig4

Results from 100 healthy volunteers receiving KZR-616 support development in autoimmune disorders

Consistent and reproducible pharmacology

- Target inhibition achieved at doses ≥30mg
- Similar PK and PD with 2 distinct drug product formulations
- Biologic activity established; consistent with preclinical models

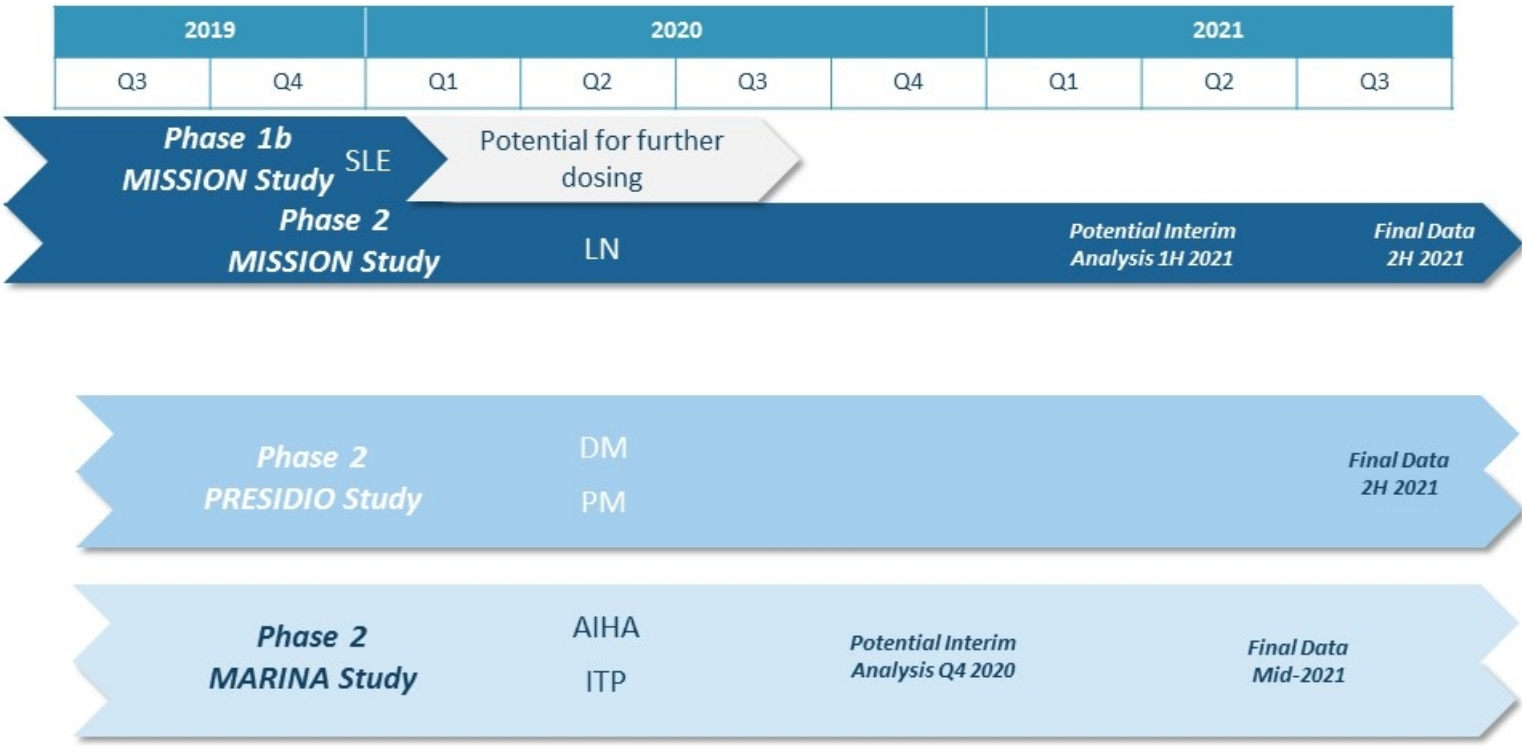
Distinct Safety Profile vs. Dual Inhibitors

- No prolonged hematologic AEs or laboratory abnormalities
- Normal renal function
- Single case of transient CV changes at 1st dose
- No peripheral neuropathy

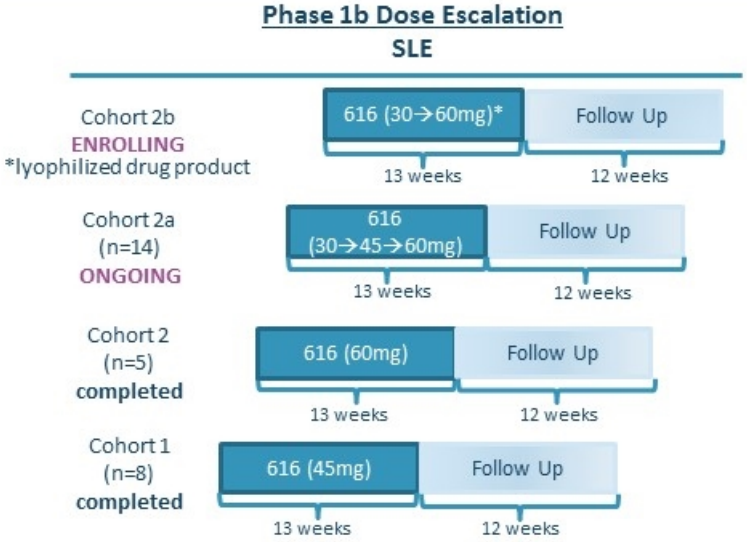
Encouraging Safety and Tolerability Profile

- Tolerable doses up to 75mg
- Most (>75%) AEs related to transient injection site reactions
- 1st dose effect (transient nausea/vomiting) managed with step-up dosing

KZR-616 is being evaluated in 5 separate autoimmune indications across 3 different Phase 2 clinical trials



Ph1b/2 MISSION Study: Modulator of the Immunoproteasome for Systemic Lupus with and without Nephritis



Endpoints

1º: Safety

2º: Recommended Phase 2 doses, Plasma PK

Exploratory: Efficacy, PD, Biomarkers, Pharmacogenomics

Poster presentation at ACR 2019 on 11/12/2019

Abstract #2520

Study NCT03393013

BILAG=British Isles Lupus Assessment Group Index; DLT=dose-limiting toxicity; PD=pharmacodynamics; Pred=prednisone; SLEDAI-2K=SLE Disease Activity Index 2000; SOC=standard of care

Initial data from the Ph 1b portion of the MISSION study supports advancement into Ph 2 trials across multiple indications

Safety and Tolerability	• KZR-616 dosed at both 45 and 60 mg (with step-up dosing) well tolerated for 13 weeks of treatment • Largely avoided toxicities seen with dual proteasome inhibitors • Encouraging early data suggests low infection rate
Efficacy	• Consistent and broad improvement seen across all measures of disease activity at week 13
PK and PD	• Consistent, dose proportional PK • Target levels of immunoproteasome inhibition were reached with all dose levels

Treatment Emergent Adverse Events (TEAEs) in the MISSION Study are consistent with those seen in Healthy Volunteer Study (HVS)

n (%, # of AEs)	Cohort 1 45 mg N=8	Cohort 2 60 mg N=5	Cohort 2a 30→60 mg N=11	All KZR-616 N=24
TEAEs	8 (100, 44)	5 (100, 58)	7 (64, 47)	20 (83, 149)
TEAEs ≥Grade 3	0 (0, 0)	1 (20, 1)	1 (9, 1)	2 (8, 2)
TEAEs leading to drug discontinuation	0 (0, 0)	1 (20, 1)	2 (18, 2)	3 (13, 3)
Serious TEAEs	0 (0, 0)	1 (20, 1)*	1 (9, 1)^	2 (8, 2)
Serious infectious TEAE	0 (0, 0)	0 (0, 0)	1 (9, 1)^	1 (4, 1)
Non-serious infectious TEAE	1 (13, 1)	0 (0, 0)	2 (18, 2)	3 (13, 3)
Any injection site reaction (ISR) TEAE	6 (75, 35)	4 (80, 19)	4 (36, 24)	14 (58)
Any non-ISR TEAE in ≥2 pts				
Nausea	2 (25, 2)	4 (80, 6)	3 (27, 4)	9 (38, 12)
Vomiting	1 (13, 1)	5 (100, 7)	2 (18, 3)	8 (33, 11)
Headache	1 (13, 1)	2 (40, 13)	1 (9, 1)	4 (17)
Dizziness	1 (13, 1)	2 (40, 2)	0 (0, 0)	3 (13)
Pyrexia	0 (0, 0)	2 (40, 2)	1 (9, 4)	3 (13)
Chills	0 (0,0)	1 (20, 1)	1 (9, 2)	2 (8)

1st dose effect

*1 case of thrombotic microangiopathy

^1 case of herpes zoster

KZR-616 shows broad immunomodulatory activity in evaluable patients at 13 weeks (n=11)

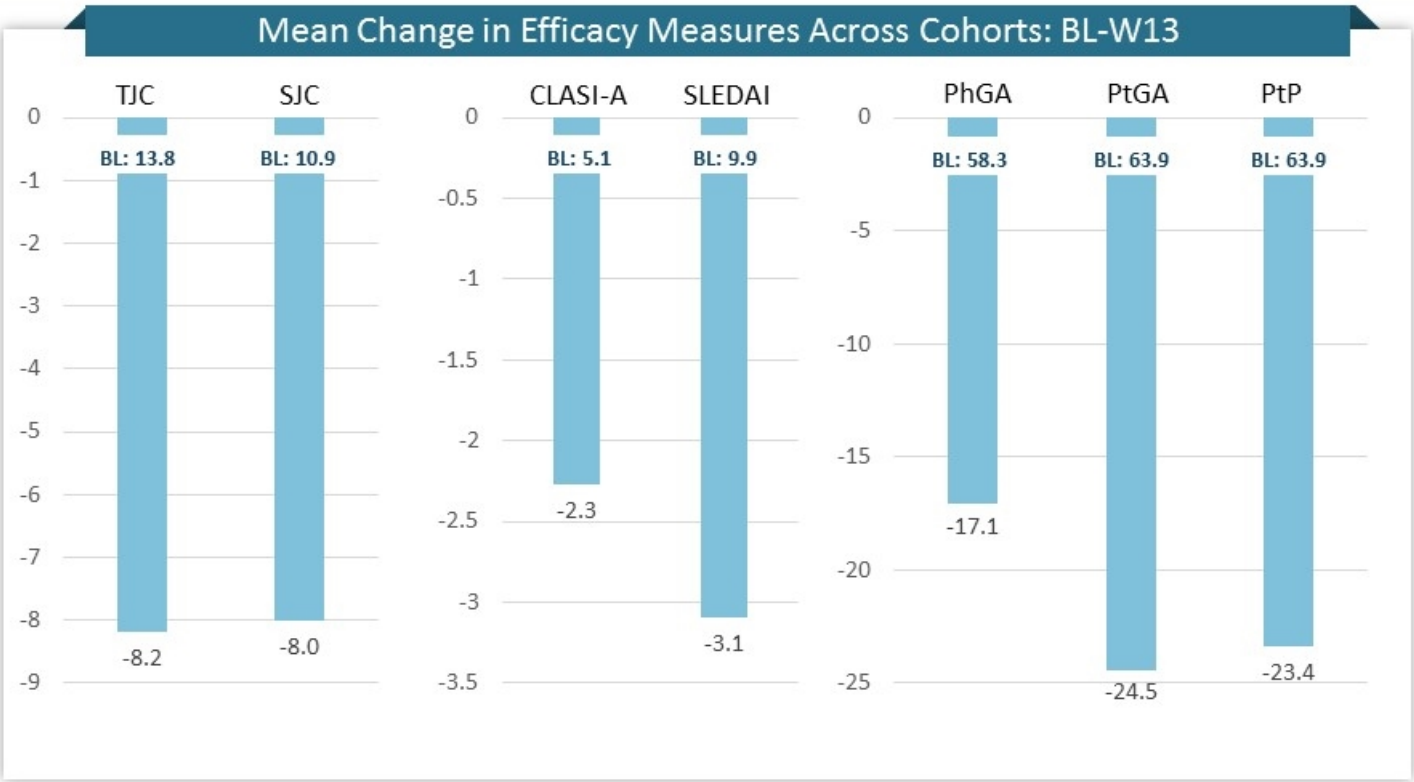
Efficacy Measures	KZR-616
TJC/SJC (joints)	55% of evaluable pts had ≥50% improvement on either TJC OR SJC
CLASI-A (mucocutaneous)	57% of evaluable pts with CLASI-A ≥4 at BL (n=7) had decrease ≥4 points
SLEDAI	82% of evaluable pts had a decrease ≥2 points; 45% had a decrease ≥4 points
PhGA/PtGA/PtP	55%, 91%, and 91% of evaluable pts had ≥10-point reduction, respectively
Biomarker	50% of evaluable pts with low complement levels at BL (n=6) had resolution

Safety population (received ≥1 dose of KZR-616) (N=24)

Pts receiving ≥1 month of dosing with KZR-616 (n=16)

Pts completing 13 weeks of treatment (n=11)

Broad and consistent improvement shown across all measures of efficacy in evaluable patients at 13 weeks

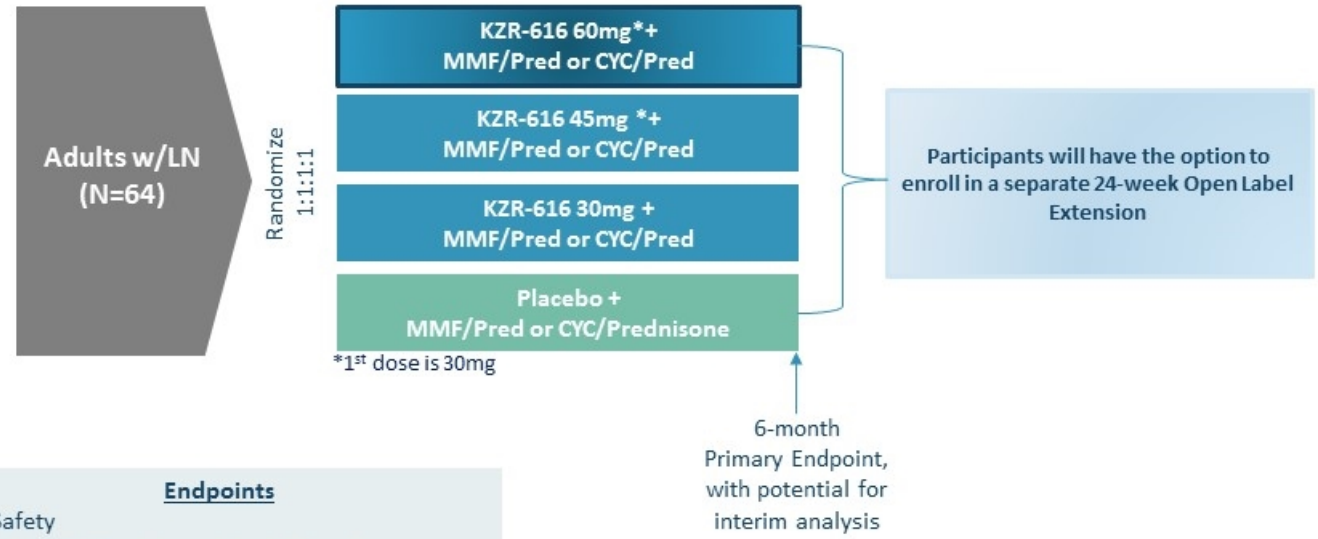


TJC=tender joint count; SJC=Swollen Joint Count; CLASI-A=Cutaneous Lupus Erythematosus Severity Index-Activity; SLEDAI=Systemic Lupus Erythematosus Disease Activity Index 2000; PhGA/PtGA/PtP=Physician Global Assessment/Patient Global Assessment/Patient assessment of pain (see Appendix for definitions of each)

Ph2 MISSION Study: Enhanced clinical trial design is more robust and in line with other LN studies

Amended Phase 2 Design

(pending approval of protocol amendment)



Endpoints

1°: Safety

2°: Efficacy (Complete and partial renal response rates, SLEDAI-2K, corticosteroid use)

Exploratory: PD, Biomarkers, Pharmacogenomics

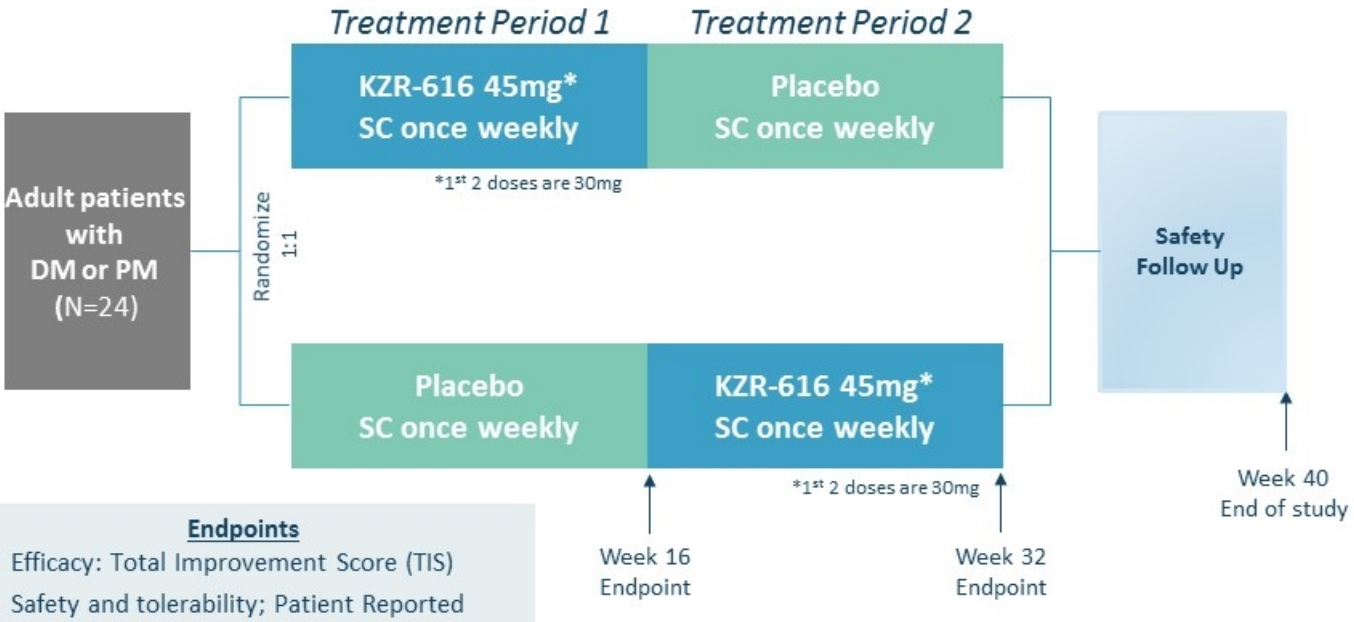
Study NCT03393013

PD=pharmacodynamics; Pred=prednisone; CYC= cyclophosphamide; MMF=Cellcept/mycophenolate mofetil; SLEDAI-2K=SLE Disease Activity Index 2000

Key protocol changes should improve recruitment and garner a more robust and meaningful data read on '616

Trial Feature	Original	New
Treatment duration	3 months	6 months + (separate 6-month open-label extension)
Number of patients	48	64
Dose levels	30 and 45mg	30, 45, 60mg
Background medication	MMF + steroids only	MMF + steroids or CYC + steroids
Inclusion/Exclusion criteria	Enrollment 1-3 months into induction	Enrollment 0-3 months into induction
	6-month biopsy window	12-month biopsy window
Site Expansion	16 (predominantly US)	60+ (global)
Data analysis	Primary endpoint @3 mo	Primary endpoint @6 mo w/potential interim analysis

Ph 2 PRESIDIO Study: Placebo-controlled Study of the Efficacy and Safety of Treating Dermatomyositis and Polymyositis with the Selective Immunoproteasome Inhibitor KZR-616



Endpoints

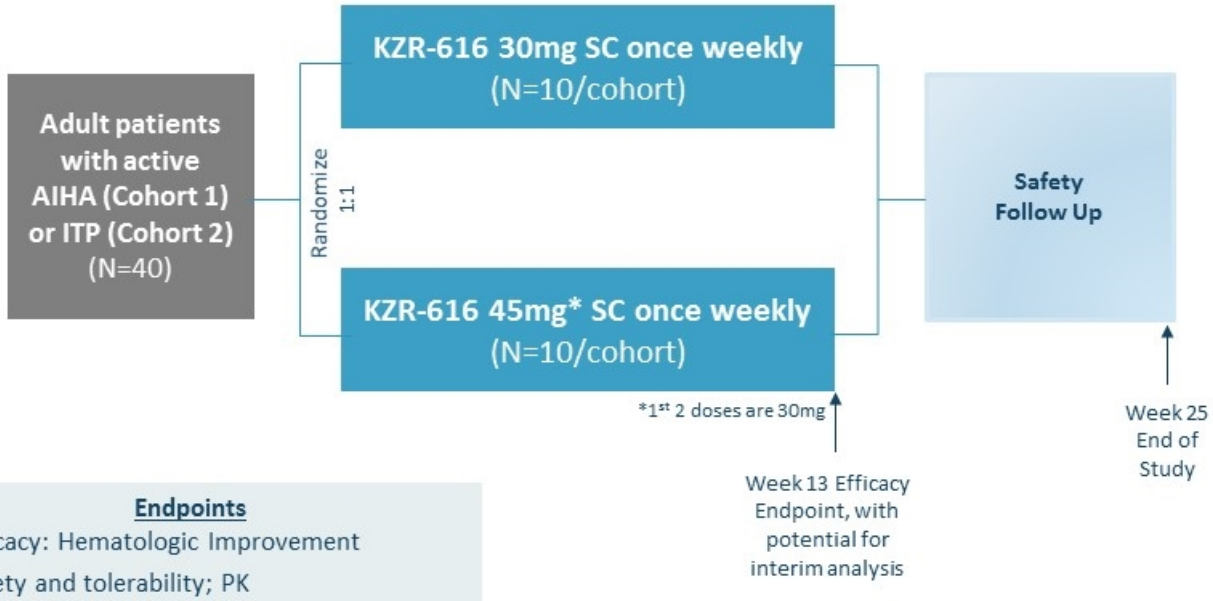
1º: Efficacy: Total Improvement Score (TIS)

2º: Safety and tolerability; Patient Reported Outcomes (PROs), PK

Exploratory: Biomarkers, PK/PD relationship

Study NCT04033926

Ph 2 MARINA Study: Modulator of the Immunoproteasome for Autoimmune Hemolytic Anemia and Immune Thrombocytopenia



Endpoints

1º: Efficacy: Hematologic Improvement

2º: Safety and tolerability; PK

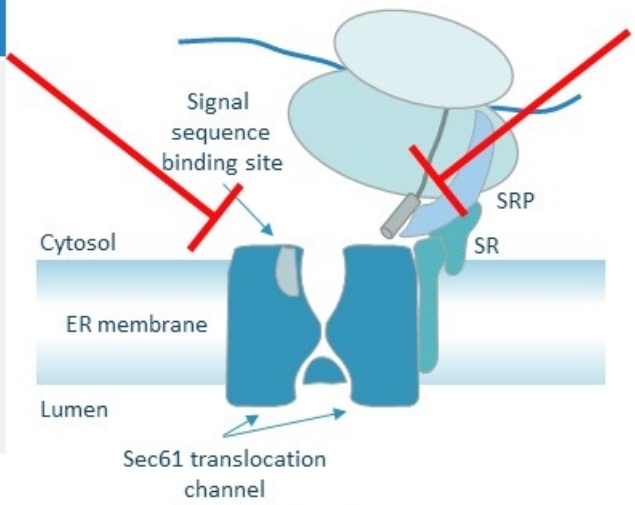
Exploratory: Biomarkers, PK/PD relationship

Study NCT04039477

Kezar has multiple small molecule approaches to modulating protein secretion at the Sec61 Translocon

Multiple Protein Secretion Inhibitors

- Compelling anti-cancer activity in pre-clinical models
- Potential for multiple clinical candidates
- Tunable selectivity



Specific Protein Secretion Inhibitors

- Target selective approach
- High value / validated targets
- Applications in oncology and autoimmunity

Clinical candidate nomination expected in Q4 2019

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