
**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): June 17, 2024

Keros Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-39264
(Commission
File Number)

81-1173868
(I.R.S. Employer
Identification No.)

1050 Waltham Street, Suite 302

Lexington, Massachusetts
(Address of principal executive offices)

02421
(Zip Code)

Registrant's telephone number, including area code: (617) 314-6297

Not applicable

(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:

- 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, \$0.0001 par value per share	KROS	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 8.01 Other Events.

On June 17, 2024, Keros Therapeutics, Inc. (the "Company") issued a press release announcing additional data from its two ongoing Phase 2 clinical trials of elritercept (KER-050), one in patients with very low-, low-, or intermediate-risk myelodysplastic syndromes ("MDS") and one in patients with myelofibrosis ("MF"), at the 29th Annual Hybrid Congress of the European Hematology Association ("EHA"), held virtually and in person from June 13 through 16, 2024. In addition, the Company presented preclinical data showing that, in an animal model of MF, a research form of elritercept promoted erythropoiesis, mitigated anemia associated with MF, improved anemia associated with ruxolitinib therapy and improved muscle mass and function. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

During a conference call and webcast scheduled to be held at 8:00 a.m. Eastern time on June 17, 2024, the Company's management will discuss the additional data from its two ongoing Phase 2 clinical trials of elritercept, one in patients with MDS and one in patients with MF, as well as additional updates to the Company's pipeline. A copy of the presentation for the conference call and webcast is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 17, 2024.
99.2	Investor Presentation dated June 2024.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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.

KEROS THERAPEUTICS, INC.

By: /s/ Jasbir Seehra
Jasbir Seehra, Ph.D.
Chief Executive Officer

Dated: June 17, 2024

Keros Therapeutics Presents Clinical Data from its Elritercept (KER-050) Program at the 29th Annual Hybrid Congress of the European Hematology Association

- *Elritercept continued to demonstrate a durable transfusion independence in lower-risk myelodysplastic syndromes, including in patients with high transfusion burden*
- *Durable clinical responses were associated with improvements in patient-reported measures of fatigue*
- *Data from ongoing Phase 2 clinical trial in myelofibrosis continue to demonstrate that elritercept can not only ameliorate ineffective hematopoiesis and address cytopenias, but also provide broader clinical benefit, as supported by observed reductions in spleen volume and improved total symptom scores*
- *Keros will host a corporate update call and webcast today, June 17, 2024, at 8:00 a.m. ET*

LEXINGTON, Mass., Jun. 17, 2024 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. ("Keros" or the "Company") (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the transforming growth factor-beta ("TGF- β ") family of proteins, today announced that it presented additional data from its two ongoing Phase 2 clinical trials of elritercept (KER-050), one in patients with very low-, low-, or intermediate-risk myelodysplastic syndromes ("MDS") and one in patients with myelofibrosis ("MF"), at the 29th Annual Hybrid Congress of the European Hematology Association ("EHA"), held in person in Madrid, Spain and virtually from June 13 through 16, 2024. In addition, Keros presented preclinical data showing that, in an animal model of MF, a research form of elritercept promoted erythropoiesis, mitigated anemia associated with MF, improved anemia associated with ruxolitinib therapy and improved muscle mass and function.

"The data we presented at EHA continues to show an encouraging broad profile of elritercept and supports its potential to treat not just the disease-associated cytopenias, but also impact the pathogenesis of MDS and MF," said Jasbir S. Sehra, Ph.D., President and Chief Executive Officer. "We are excited by the results we presented, including the durability of transfusion independence observed with elritercept, and are excited to progress towards initiating a registrational Phase 3 clinical trial in MDS following positive feedback from the U.S. Food and Drug Administration."

Select Clinical Presentations

- *Durable Clinical Benefit with Elritercept (KER-050) Treatment: Findings From an Ongoing Phase 2 Trial in Participants with Lower-Risk MDS*

This ongoing, open-label, two-part, Phase 2 clinical trial is evaluating elritercept in patients with very low-, low-, or intermediate-risk MDS. As of April 3, 2024 (the "data cut-off date"), 87 patients had received at least one dose of elritercept at the recommended Part 2 dose ("RP2D") (collectively, the "safety population"). Of these patients in the safety population, 81 had completed at least 24 weeks of treatment or discontinued as of the data cut-off date (collectively, the modified intent-to-treat 24-week population, or the "mITT₂₄ patients"). Data for hematological response and markers of hematopoiesis were presented from exploratory analyses of these mITT₂₄ patients. All data presented from this trial is as of the data cut-off date.

Of the 87 patients in the safety population, 57.5% (n=50) were high transfusion burden ("HTB") while 25.3% (n=22) were low transfusion burden and 17.2% (n=15) were non-transfused ("NT").

Elritercept was observed to be generally well-tolerated in the safety population. There were three cases of fatal treatment-emergent adverse events (“TEAEs”) in the trial that were all deemed unrelated to treatment. The most commonly reported TEAEs (in $\geq 15\%$ of patients) were diarrhea, fatigue, dyspnea, dizziness, COVID-19, nausea and anemia. No patients had progressed to acute myeloid leukemia.

55.6% (n=45/81) of the mITT₂₄ patients achieved an overall erythroid response over the first 24 weeks of treatment, which is defined as meeting either modified International Working Group 2006 Hematological improvement-erythroid (“HI-E”) or transfusion independence (“TI”) for at least eight weeks in transfusion-dependent patients who required ≥ 2 red blood cell (“RBC”) units transfused at baseline.

Additional data from the mITT₂₄ patients include:

- 41.3% (n=26/63) of the TI-evaluable patients achieved TI for at least eight weeks over the first 24 weeks of treatment. 16 of those 26 patients (61.5%) achieved TI for at least 24 weeks over the first 48 weeks of treatment.
- Of the patients with HTB, 34.8% (n=16/46) achieved TI for at least eight weeks during the first 24 weeks of treatment. Eight of those 16 patients (50.0%) achieved TI for at least 24 weeks over the first 48 weeks of treatment.
- Of the TI-evaluable patients with baseline erythropoietin level less than 500 U/L, 50.0% (n=25/50) achieved TI for at least eight weeks over the first 24 weeks of treatment. Of the TI-evaluable patients with baseline erythropoietin level less than 500 U/L and HTB, 42.9% (n=15/35) achieved TI for at least eight weeks over the first 24 weeks of treatment.
- The median duration of transfusion independence was not met as of the data-cutoff date. 61.5% (n=16/26) of patients with a TI response had ongoing TI as of the data-cutoff. Of the patients that achieved TI, 42.3% (n=11/26) had responses of greater than one year, with all ongoing as of the data cut-off date.

The FACIT-Fatigue scale, a measure of self-reported fatigue and its impact upon daily activities and function, was utilized to assess health-related quality of life in 62 of the mITT₂₄ patients who were TI-evaluable and with baseline FACIT-Fatigue assessment. A difference of three in the FACIT-Fatigue scale is considered a minimally clinically important difference. In this group, patients who achieved TI had durable and clinically meaningful improvements in self-reported fatigue. Patients achieving TI of 24 weeks or longer had a mean change from baseline of 6.6 (n=12) versus patients who did not achieve TI of at least 24 weeks, who reported a mean change from baseline of -2.7 (n=25), for a mean difference of 9.4.

The majority of patients enrolled in this ongoing trial had HTB and/or multi-lineage dysplasia, indicating a difficult-to-treat trial population. Durable TI responses continue to be observed in a broad range of patients with lower-risk MDS, including in those with HTB, which support the potential for elritercept to ameliorate ineffective hematopoiesis across multiple lineages in patients with MDS. Patients who achieved TI showed clinically meaningful improvements in FACIT-Fatigue scores, indicating that elritercept may improve quality of life in patients with lower-risk MDS.

- *Elritercept (KER-050) Demonstrated Potential to Treat Myelofibrosis and Mitigate Ruxolitinib-Associated Cytopenias in the Phase 2 RESTORE Trial*

This ongoing, open-label, two-part Phase 2 clinical trial is evaluating elritercept administered with or without ruxolitinib in patients with MF who have anemia and were either currently on, failed, or ineligible for ruxolitinib at baseline. Safety data are presented for all patients that received at least one dose of elritercept (n=54) as of the data cut-off date. Evaluations of markers of hematopoiesis and anemia over 12 weeks, along with measurements of spleen volume and symptom scores (by the MF-

symptom assessment form-Total Symptom Score, or “MF-SAF-TSS”) over 24 weeks, were presented for dose levels 1 through 4 in Part 1 and the RP2D, ranging from 0.75 mg/kg to 5.0 mg/kg (collectively, the “efficacy evaluable patients”). Enrollment of Part 1 of the trial, the dose escalation portion, is complete. Part 2, the dose expansion portion, is open and enrolling with a RP2D of 3.75 mg/kg with the option to up-titrate to 5.0 mg/kg. All data presented from this trial is as of the data cut-off date.

Elritercept was generally well-tolerated by the safety population. There were four cases of fatal TEAEs in the trial that were each deemed unrelated to treatment. The most commonly reported TEAEs (in $\geq 15\%$ of patients) were thrombocytopenia and diarrhea. The majority of treatment-related TEAEs were mild to moderate, with three patients experiencing Grade 3 or higher treatment-related TEAEs.

Additional data from the efficacy evaluable patients include:

- Increases in hemoglobin were observed in the majority of evaluable non-transfusion dependent patients in both arms over a 12-week period within the first 24 weeks, suggesting that elritercept has the potential to address anemia due to MF and ruxolitinib-associated anemia.
- 60.6% (n=20/33) of patients that received at least three RBC units per 12 weeks at baseline in both arms and all dose levels tested showed reductions in transfusion burden over 12 weeks within the first 24 weeks. 60% (n=12/20) of the patients who showed reductions in transfusion burdens had a reduction of 50% or greater in the number of transfusions.
 - Of the patients receiving 3.0 mg/kg of elritercept or higher in combination with ruxolitinib, 72.7% (n=8/11) had reduction of 50% or greater and 45.5% (n=5/11) of patients achieved TI.
- At Week 24, some reduction in spleen volume was observed in 52.9% (n=9/17) of patients with baseline spleen size ≥ 450 cm³ and a Week 24 spleen assessment, including three patients who had reductions of 35% or greater. Reductions in spleen volume in the combination arm generally occurred without an increase in ruxolitinib dose.
- At Week 24, some reduction in disease symptoms was observed in a majority of patients with at least two symptoms with an average score ≥ 3 or an average total score of ≥ 10 on the MF-SAF-TSS questionnaire at baseline and a week 24 MF-SAF-TSS assessment. Three patients had reductions of at least 50%, including two in the monotherapy arm and one in the combination arm.

The data support the potential of elritercept to ameliorate ineffective hematopoiesis and address cytopenias due to MF and associated with ruxolitinib, and provide broader clinical benefit in patients, as supported by the observed reduction in spleen volume and improvement in total symptom scores.

Conference Call and Webcast Information

Keros will host a corporate update conference call and webcast today, June 17, 2024, at 8:00 a.m. Eastern time, to discuss the additional data from its two ongoing Phase 2 clinical trials of elritercept, one in patients with MDS and one in patients with MF, as well as additional updates to the Company's pipeline.

The conference call will be webcast live at: https://event.webcasts.com/starthere.jsp?ei=1673414&tp_key=3e89bee7b4. The live teleconference may be accessed by dialing (877) 407-0309 (domestic) or (201) 389-0853 (international). An archived version of the call will be available in the Investors section of the Keros website at <https://ir.kerostx.com/> for 90 days following the conclusion of the call.

About the Ongoing Phase 2 Clinical Trial of Elritercept in Patients with MDS (NCT04419649)

Keros is conducting an open label, two-part, multiple ascending dose Phase 2 clinical trial to evaluate elritercept in patients with very low-, low-, or intermediate-risk MDS who either have or have not previously received treatment with an erythroid stimulating agent.

The primary objective of this trial is to assess the safety and tolerability of elritercept in patients with MDS that are RS positive or non-RS. The primary objective of Part 2 of this trial is confirmation of the safety and tolerability of the RP2D (3.75 mg/kg and 5.0 mg/kg). The secondary objectives of this trial are to evaluate the pharmacokinetics, pharmacodynamics and efficacy of elritercept.

About the Ongoing Phase 2 Clinical Trial of Elritercept in Patients with MF-Associated Cytopenias (RESTORE trial; NCT05037760)

Keros is conducting an open label, two-part, multiple ascending dose Phase 2 clinical trial to evaluate elritercept as a monotherapy and in combination with ruxolitinib in patients with MF-associated cytopenias.

The primary objective of this trial is to assess the safety and tolerability of elritercept in patients with MF-associated cytopenias. The primary objective of Part 2 of this trial is confirmation of the safety and tolerability of the RP2D (3.75 mg/kg and 5.0 mg/kg). The secondary objectives of this trial are to evaluate the pharmacokinetics, pharmacodynamics and efficacy of elritercept administered with or without ruxolitinib.

About Elritercept

Keros' lead product candidate, elritercept, is an engineered ligand trap comprised of a modified ligand-binding domain of the TGF- β receptor known as activin receptor type IIA that is fused to the portion of the human antibody known as the Fc domain. Elritercept is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with MF.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the TGF- β family of proteins. We are a leader in understanding the role of the TGF- β family of proteins, which are master regulators of the growth, repair and maintenance of a number of tissues, including blood, bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, we have discovered and are developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros' lead product candidate, elritercept, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with MF. Keros' second product candidate, cibotcept (KER-012), is being developed for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders. Keros' third product candidate, KER-065, is being developed for the treatment of obesity and for the treatment of neuromuscular diseases.

Cautionary Note Regarding Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "potential," "progress" and "will" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros' expectations regarding its growth, strategy, progress and the design, objectives,

endpoints and timing of its clinical trials for elritercept, including its regulatory plans; the potential of elritercept to treat beyond MF- and MDS-associated cytopenias to have a direct effect on the pathogenesis of MF and MDS, respectively; the potential of KER-050 to ameliorate ineffective hematopoiesis across multiple lineages in patients with MDS and to improve quality of life in patients with lower-risk MDS; and the potential of KER-050 to address anemia due to MF and ruxolitinib-associated anemia. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Keros' limited operating history and historical losses; Keros' ability to raise additional funding to complete the development and any commercialization of its product candidates; Keros' dependence on the success of its product candidates, elritercept, cibotercept and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; Keros' ability to obtain, maintain and protect its intellectual property; and Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

These and other risks are described more fully in Keros' filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2024, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Keros undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact:

Justin Frantz
jfrantz@kerostx.com
617-221-6042



Corporate Update

June 2024



Disclaimer

Statements contained in this presentation regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as “anticipates,” “believes,” “expects,” “intends,” “plans,” “potential,” “projects,” “would” and “future” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros’ expectations regarding its growth, strategy, progress and the design, objectives, expected results and timing of its preclinical studies and clinical trials for KER-050, KER-012 and KER-065, including its regulatory and enrollment plans; and the potential of Keros’ product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Keros’ limited operating history and historical losses; Keros’ ability to raise additional funding to complete the development and any commercialization of its product candidates; Keros’ dependence on the success of its product candidates, KER-050, KER-012 and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; Keros’ ability to obtain, maintain and protect its intellectual property; and Keros’ dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

These and other risks are described more fully in Keros’ filings with the Securities and Exchange Commission (“SEC”), including the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2024, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Except to the extent required by law, Keros undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

The trademarks included in this presentation are the property of the owners thereof and are used for reference purposes only.



Focused on Transforming the Lives of a Wide Range of Patients with Disorders Linked to Dysfunctional TGF- β Superfamily Signaling

Keros is a clinical-stage biopharmaceutical company
 Developing potentially differentiated product candidates designed to alter transforming growth factor-beta (TGF- β) signaling and target pathways critical for the growth, repair and maintenance of a number of tissue and organ systems

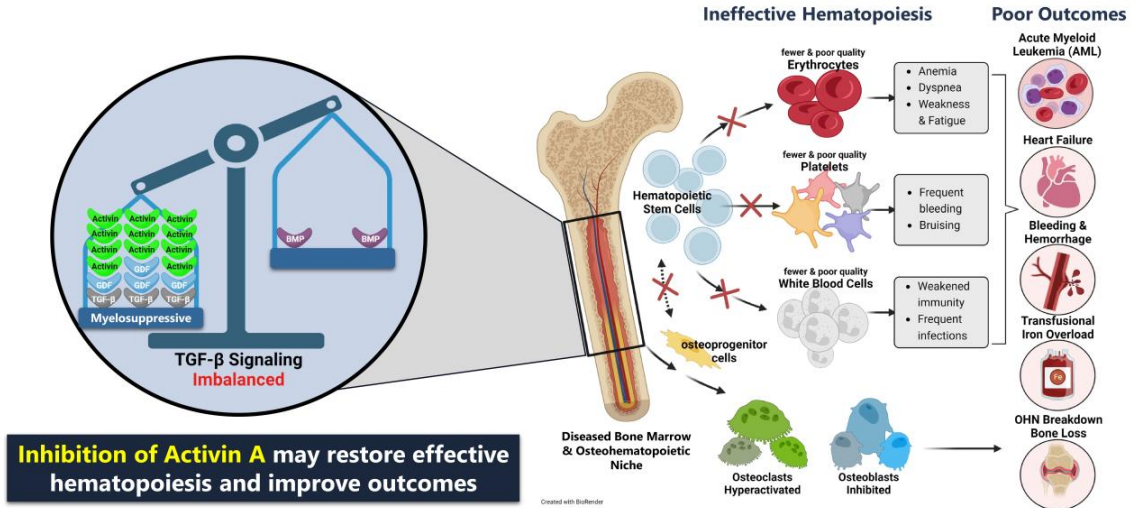
We believe our product candidates have the potential to unlock the full therapeutic benefits of modulating the TGF- β superfamily and provide disease-modifying benefit to patients





Hematology

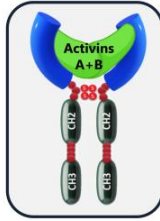
Imbalanced TGF- β Signaling in Bone Marrow Results in Ineffective Hematopoiesis and Poor Outcomes in Both MDS and MF^{1,2,3}



1. Verma A, et al. J Clin Inv 2020; 2. Portale F, et al. Haematologica. 2019; 3. Rambaldi B, et al. Ann Hematol. 2021
 BMP = bone morphogenetic protein; GDF = growth differentiation factor; OHN = osteohematopoietic niche

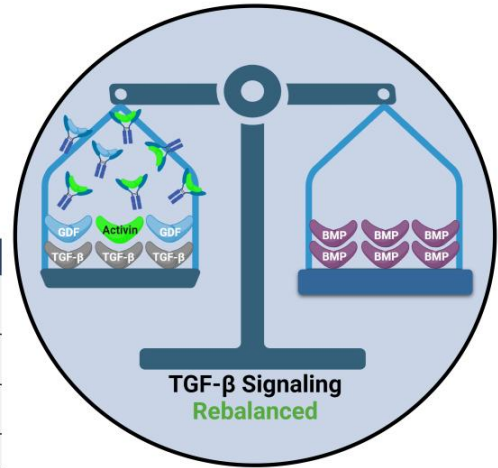







Elritercept is Designed to Target Bone Marrow Disorders of Ineffective Hematopoiesis Including MDS and MF



Elritercept (KER-050)

- Designed to inhibit select TGF-beta superfamily ligands, including **Activin A**, which has been associated with ineffective hematopoiesis, inflammation, and driving disease pathogenesis and progression^{1,2,3}



Domain	Potential Effect
 Erythropoiesis	ALL stages of differentiation and maturation ⁴
 Thrombopoiesis	ALL stages of differentiation and maturation ⁵
 Bone	Increased bone formation ⁴ ; potential to improve the osteohematopoietic niche (OHN)
 Iron Metabolism	Improved iron utilization ⁶
 Cardiovascular	Ameliorated cardiac strain ⁶

1. Verma A, et al. J Clin Inv 2020; 2. Portale F, et al., Haematologica. 2019; 3. Phillips, D et al. Cytokine Growth factor Rev. 2009; 4. Moses et al. American Society of Hematology, 2022; 5. Moses et al. Gordon Research Conference: Cell Biology of Megakaryocytes and Platelets. 2023 6. Chee et al. American Society of Hematology, 2023



Elritercept (KER-050)

**Investigational Treatment for Anemia and
Thrombocytopenia in Patients with
Myelodysplastic Syndromes**

*Ongoing Phase 2 Clinical Trial of KER-050 for the
Treatment of Anemia in Patients with Very Low-,
Low- or Intermediate-Risk Myelodysplastic Syndromes*

Myelodysplastic Syndromes (MDS)



MDS

MDS is a collection of bone marrow disorders characterized by ineffective hematopoiesis and peripheral cytopenias.



Clinical Consequences

The clinical consequences of MDS include anemia, bleeding, iron overload, cardiovascular disease and progression to acute myeloid leukemia (AML).



Survival Ranges

Median survival ranges from approximately nine years for very low-risk patients to less than a year for high-risk patients.

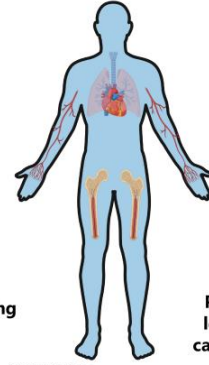


Scope

In the United States, there are 60,000 to 170,000 patients living with MDS and 15,000 to 20,000 new cases of MDS reported each year.

QoL = quality of life

Impact of MDS



Cytopenias including severe anemia

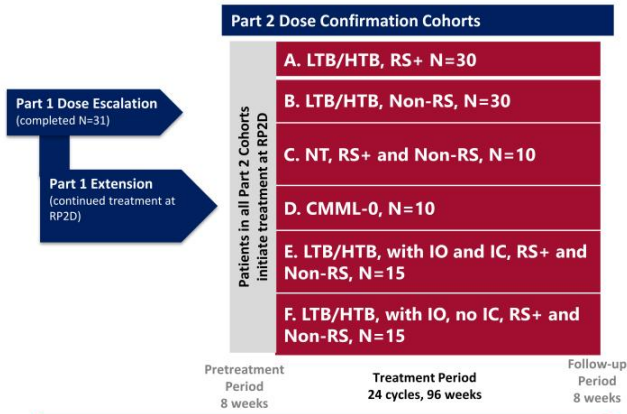
Progressive disease leading to AML and cardiovascular disease

Created with BioRender

Severe fatigue and decreased QoL



Ongoing Phase 2 Clinical Trial of Elritercept for the Treatment of Anemia in Patients with Very Low-, Low- or Intermediate-Risk MDS



Response data are presented for the modified intent to treat 24-week population (mITT₂₄) that includes RP2D patients with at least 24 weeks of KER-050 treatment or who have discontinued (n=81)

Elritercept administered subcutaneously once every four weeks (Q4W)

Primary Objective:

- Assess safety and tolerability of elritercept

Key Eligibility Criteria:

- MDS per 2016 WHO criteria, RS+ or non-RS, very-low, low, or intermediate risk disease (LR-MDS) by IPSS-R with anemia (NT, LTB, HTB)
 - CMML in Cohort D

Select Efficacy Endpoints:

- IWG 2006 Hematological improvement-erythroid (HI-E):
 - Hemoglobin increase of ≥ 1.5 g/dL for 8 weeks (in NT and LTB patients)
 - Reduction of ≥ 4 red blood cell (RBC) units transfused over 8 weeks compared to baseline (in HTB patients)
- Transfusion independence (TI) for at least 8 weeks in patients who require ≥ 2 RBC units transfused at baseline

Ongoing Trial – Status as of Data Cut-off Date:

- Part 1 Extension Ongoing
- RP2D: 3.75 mg/kg with the ability to titrate to 5 mg/kg Q4W
- RP2D experienced patients: N=87
 - 7 (8.0%) patients received < 3 doses
 - 46 (52.9%) patients were ongoing and remained on treatment
 - Median duration of treatment = Approx. 42 weeks (Range = 1 to 145 weeks)
 - 39 (44.8%) patients received ≥ 12 doses

Data are presented as of a data cut-off date of April 3, 2024.

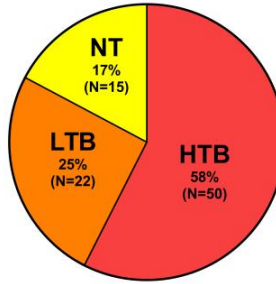
RP2D = Recommended Part 2 Dose; CMML: chronic myelomonocytic leukemia; high transfusion burden (HTB): ≥ 4 units of RBC/8 weeks for hemoglobin (Hgb) ≤ 9 g/dL; low transfusion burden (LTB): 1-3 units of RBC/8 weeks for Hgb ≤ 9 g/dL; non-transfused (NT): Hgb ≤ 10 g/dL; RS = ring sideroblasts; IO = Iron Overload; IC = Iron Chelation; IPSS-R = Revised International Prognostic Scoring System



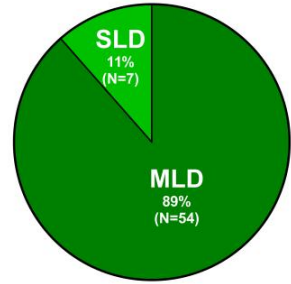
Trial Enrolled Hard-to-Treat Patients with High Disease Burden

Baseline Characteristic	RP2D (N=87)
Median Age, years (range)	74 (53-89)
Sex, n (%) male	55 (63.2)
Ring Sideroblasts Status, n (%)	
RS+	60 (69.0)
Non-RS	27 (31.0)
Prior ESA, n (%)	24 (27.6)
EPO, U/L*	
n	78
Mean (SD)	401.6 (692.1)
Median (IQR)	127.8 (50.6,309.7)
Thrombocytopenia, n (%) (platelets <150 x 10 ⁹ /L)	21 (24.1)

Baseline Transfusion Burden



Baseline Dysplasia Category**



Data are presented as of a data cut-off date of April 3, 2024.

*9 RP2D patients had missing baseline EPO; **Excludes 26 RP2D patients with unknown dysplasia category

EPO = erythropoietin; SLD = single lineage dysplasia; MLD = multi lineage dysplasia; SD = standard deviation; IQR = interquartile range



Elritercept was Generally Well-Tolerated

- **Most frequent TEAEs (\geq in 15% of patients) regardless of causality were:**
 - Diarrhea (24; 27.6%)
 - Fatigue (22; 25.3%)
 - Dyspnea (18; 20.7%)
 - Dizziness (17; 19.5%)
 - COVID-19 & Nausea (16, 18.4%)
 - Anemia (15; 17.2%)
- **Majority of TEAEs were mild (Grade 1) to moderate (Grade 2)**
- **4 treatment-related TESAEs of injection site reaction (Grade 2), dyspnea (Grade 3), syncope (Grade 3) and gastric neoplasm (Grade 3) occurred in 1 patient each**
 - Gastric neoplasm, dyspnea and syncope were assessed as not related to study treatment by the Sponsor due to underlying comorbidities
- **Fatal TESAEs (cardiac failure, MI and sudden death) occurred in 3 (3.4%) patients; both were assessed as unrelated by the PI and the Sponsor**
- **No patients progressed to AML**

Category	RP2D (N=87) n (%)
Any TEAE	85 (97.7)
Any treatment-related TEAE*	37 (42.5)
Any TESAЕ	38 (43.7)
Any treatment-related TESAЕ	4 (4.6)
Any TEAE leading to death	3 (3.4)
Any TEAE leading to KER-050 discontinuation*	13 (14.9)

*Treatment-related TEAEs leading to KER-050 discontinuation: injection site reaction, platelet count increased, and dyspnea

Unrelated TEAEs leading to KER-050 discontinuation: nodular melanoma, NSCLC, MI, dementia Alzheimer's type, dyspnea, cardiac failure, sudden death, lymphocytic leukemia, COPD and cardiac failure congestive (both in 1 patient)

Treatment-related = considered to be related to the study treatment by the treating investigator. Number and percent of patients with events were summarized.

Data are presented as of a data cut-off date of April 3, 2024.

AML = acute myeloid leukemia; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; NSCLC = non-small cell lung cancer; TEAE = treatment emergent adverse event; TESAЕ = treatment emergent serious adverse event



Hematologic Responses Observed in Broad Array of Patients Treated with Elritercept (Weeks 0 to 24)

Responders/N (%)	mITT ₂₄ ^a		mITT ₂₄ + EPO < 500 U/L ^b	
	All (N=81)	HTB (N=46)	All (N=66)	HTB (N=35)
Overall Response^c	45/81 (55.6)	23/46 (50.0)	40/66 (60.6)	20/35 (57.1)
Modified IWG 2006 HI-E^d	40/81 (49.4)	22/46 (47.8)	35/66 (53)	19/35 (54.3)
RS+	33/57 (57.9)	19/33 (57.6)	29/51 (56.9)	16/29 (55.2)
non-RS	7/24 (29.2)	3/13 (23.1)	6/15 (40)	3/6 (50)
TI ≥ 8 weeks^e	26/63 (41.3)	16/46 (34.8)	25/50 (50.0)	15/35 (42.9)
RS+	22/45 (48.9)	13/33 (39.4)	21/40 (52.5)	12/29 (41.4)
non-RS	4/18 (22.2)	3/13 (23.1)	4/10 (40)	3/6 (50)

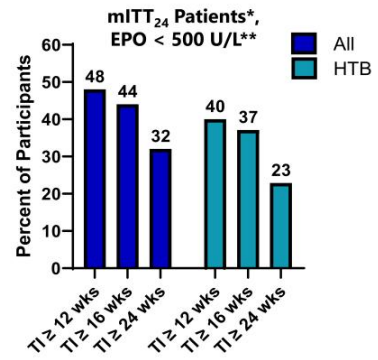
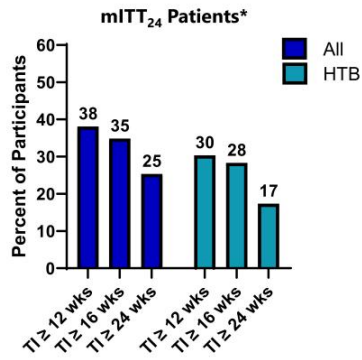
Response rates in mITT₂₄ patients with HTB were similar to those observed in the overall mITT₂₄ population, with higher rates observed in the EPO < 500 U/L population particularly in non-RS patients. These data support the potential for elritercept to treat a broad array of patients with LR-MDS

Data are presented as of a data cut-off date of April 3, 2024.

a. Includes data for weeks 0-24 in mITT₂₄ patients; b. Includes data for Weeks 0-24 in mITT₂₄ patients with baseline EPO < 500 U/L, excluding one patient with del5q MDS; c. Defined as achieving modified IWG 2006 HI-E and/or TI; d. Modified IWG 2006 HI-E = mean increase in hemoglobin ≥ 1.5 g/dL (NT+LTB) or reduction in transfusion of ≥ 4 RBC units (HTB) over 8 weeks on treatment compared to 8-week pre-treatment period; e. TI-evaluable patients received at least 2 RBC units in the 8-week pre-treatment period. TI = transfusion independence



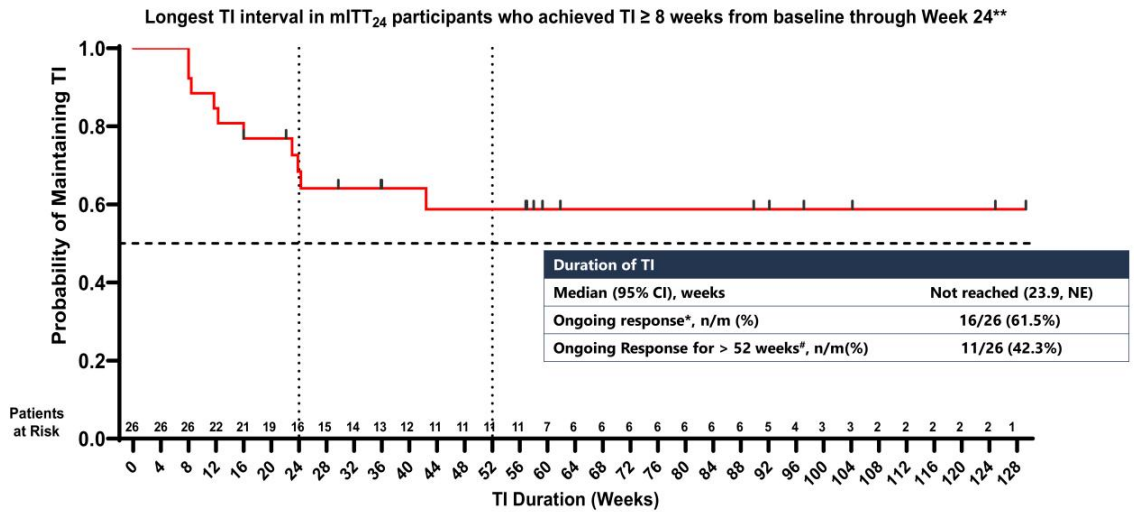
Observed Rates of TI Support Durability of Response with Elritercept Treatment (Weeks 0 to 48)



Elritercept treatment resulted in durable TI, including in patients with HTB, with relatively higher TI rates seen in patients with baseline EPO < 500 U/L

Data are presented as of a data cut-off date of April 3, 2024.
*During Weeks 0-48; **Excludes 1 patient with del5q MDS

Durable TI Responses Observed with Elritercept Treatment



Data are presented as of a data cut-off date of April 3, 2024.

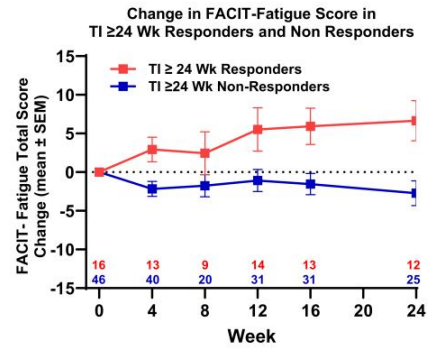
*Patients with ongoing TI response (i.e. without transfusion event) at time of cut-off are censored and denoted by vertical lines; ** RBC transfusions for elective surgery were recorded but were not counted towards baseline requirement or efficacy assessment; #6/11 (54.5%) participants with ongoing TI for > 52 weeks were HTB, including patients who had received up to 11 RBC units/8 weeks at baseline.

NE= not evaluable; CI = confidence interval



Transfusion Dependent Patients Receiving Elritercept Achieved Clinically Meaningful and Durable Improvements in FACIT-Fatigue Score

- Health-related quality of life (HRQOL) is negatively impacted by MDS^{1,2} with fatigue identified as a critically important domain to assess in patients with MDS³
 - Prolonged transfusion dependence is associated with significantly worse HRQOL and shorter overall survival³
 - Evidence suggests that worse fatigue is associated with reduced survival in MDS⁴
 - The FACIT-Fatigue scale is a validated measure of self-reported fatigue and its impact upon daily activities and function that has been widely used in MDS studies^{4,5}



Clinically meaningful improvement in fatigue defined as at least a 3-point increase in FACIT-Fatigue score

TI Response Duration	Change from Baseline in FACIT-Fatigue Score at Week 24, mean (SEM)		Mean Difference, Responder vs Non-Responder
	Responder	Non-Responder	
TI ≥24 weeks	6.6 (2.6), n=12	-2.7 (1.6), n=25	9.4

Data are presented as of a data cut-off date of April 3, 2024.

Includes data for mITT₂₄ patients with baseline FACIT-Fatigue scores (n = 1 missing) for TI ≥ 24 weeks Responder, assessed from Weeks 0 to 48;

1. Stauder, R et al., Blood. 2018; 2. Pleyer, Lisa, et al., Cancers. 2023; 3. Santini V, Et al., Clin Lymphoma Myeloma Leuk. 2018; 4. Oliva EN et al., Blood. 2021; 5. Sekeres M. et al., HemaSphere. 2023;

SEM = standard error of the mean



Summary of Elritercept Data in MDS

- In the ongoing Phase 2 clinical trial of elritercept in LR-MDS, the majority of patients enrolled had HTB or MLD indicating **a difficult-to-treat trial population**
- Elritercept was **generally well tolerated** as of the data cut-off date, with a safety profile consistent to that previously reported for this trial^{1,2}
- **Hematologic responses were observed in 56%** and **TI ≥ 8 weeks was achieved in 41% of patients**, including those with RS+ and non-RS disease
- **Durable TI responses** were observed in a broad range of patients with LR-MDS, including those with HTB, and the **median duration of response** was not reached as of the data cut-off date
- Analysis of patients with EPO < 500 U/L revealed **improved erythroid responses** across the trial population, including **in patients with HTB and/or non-RS disease**
- Patients who achieved TI showed **clinically meaningful improvements in FACIT-Fatigue scores** indicating potential for elritercept to improve **quality of life** in patients with LR-MDS

Collectively, these Phase 2 data show potential for elritercept to provide clinical benefit to a broad difficult-to-treat patient population, supporting initiation of a Phase 3 registrational trial in LR-MDS

Data are presented as of a data cut-off date of April 3, 2024.

¹ Gagounidis et al. EHA 2023; ² Diez-Campelo et al. ASH 2023



Current Landscape for Treatment of Anemia in Lower Risk MDS

RBC Transfusions

- RBC transfusions provide symptomatic relief of anemia
- Transfusion dependency is associated with iron overload, further exacerbating damage to the bone marrow and increasing risk of AML progression and cardiovascular disease
- Prolonged transfusion dependence is associated with shorter overall survival

Erythroid Stimulating Agents

- ESAs are currently first line treatment of choice, but response is limited in patients with endogenous erythropoietin levels (>200 U/L) and high transfusion burden (≥ 4 units of RBC/8 weeks)

Erythroid Maturation Agent

- Reblozyl® approved in 1st and 2nd line MDS
- In second-line treatment, only 20% of HTB patients achieved 8-week transfusion independence with Reblozyl® versus 4% with placebo¹
- In 2nd line setting, a medical reviewer of luspatercept noted “patient reported outcome (PRO) data showed no improvement in quality of life for patients who received luspatercept or who responded to luspatercept.”²

Telomerase Inhibitor

- RYTELO™ (imetelstat) approved in 2nd line HTB MDS patients
- RYTELO™ approved in patients who have not responded to or have lost response to or are ineligible for ESAs

Unmet need remains for safe and durable treatments for anemia and for treatments that address the multifaceted pathophysiology of MDS

1. Fenaux P, et al. New Eng J Med 2020; 382:140-151; 2. Luspatercept FDA Summary Basis of Approval Medical Review Page 11 4/3/2020.



Data from Third-Party Placebo-Controlled Clinical Trial in Second-Line Lower-Risk MDS Demonstrate Need for Additional Treatment Options

	MEDALIST Trial ¹ (Luspatercept Phase 3)*	
	Study Enrolled RS+ Patients Only	
	Luspatercept	Placebo
8-wk TI	38%	13%
8-wk TI in HTB patients ≥ 4 RBC units/ 8 weeks	20%	4%
Median Duration of TI in 8-week TI responders	30.6 weeks	13.6 weeks

1. Fenaux P, et al. New Eng J Med 2020; 382:140-151

*TI for 8 weeks or longer during weeks 1 through 24 in patients with baseline transfusion burden of ≥2 units/8 weeks; no EPO cap



Phase 2 Data Supports Potential for Elritercept to Achieve a Deep and Durable Efficacy Profile Differentiating from Treatment Landscape

	Elritercept Phase 2 Data (mITT ₂₄ EPO _{≤500})*	
	Study Enrolling RS+ and Non-RS Patients	
8-wk TI	50%	} Deep Response in Difficult to Treat Patients
8-wk TI in HTB patients (≥ 4 RBC units / 8 weeks)	42.9%	
24-wk TI over 48 weeks	32%	} Strong Durability of Response
Median Duration of TI in 8-week TI responders (RS and non-RS)	Not yet reached as of April 3, '24 52-week TI: 59% in 8-week TI responders	

Data are presented as of a data cut-off date of April 3, 2024.

*mITT₂₄ in patients with baseline transfusion burden of ≥2 units/8 weeks; EPO ≤500



Phase 3 Registrational Trial in MDS

Received positive feedback from the U.S. Food and Drug Administration (FDA), which resulted in general alignment on the design and endpoints for the proposed pivotal, Phase 3, placebo-controlled, clinical trial in patients with LR-MDS.

Planned Trial Population
• Very low-, low-, or intermediate risk MDS
• Anemic patients requiring transfusion
• Both RS+ and non-RS patients
• ESA naïve, intolerant or experienced; no prior Reblozyl® experience
• Baseline serum EPO level cap

Planned Endpoints
• Primary Endpoint: TI at 8 weeks within the first 24 weeks
• A key secondary outcome will be 24-week TI over 48 weeks

Plan to host investor call in the second half of 2024 to provide additional details on the Phase 3 design



Elritercept (KER-050)



Investigational Treatment for Anemia and Thrombocytopenia in Patients with Myelofibrosis

Ongoing Phase 2 Open-Label Clinical Trial to Evaluate the Safety and Efficacy of KER-050 as Monotherapy or in Combination with Ruxolitinib in Patients with Myelofibrosis

Myelofibrosis



MF

MF is a rare cancer of the bone marrow in which the marrow is replaced by scar tissue and is not able to produce healthy blood cells



Clinical Consequences

MF is characterized by ineffective hematopoiesis, an enlarged spleen, bone marrow fibrosis and shortened survival. Both anemia and thrombocytopenia are negative prognostic indicators. Anemia is prevalent in MF (one study reported anemia in 64% of patients beyond 1 year of diagnosis¹) and is associated with reduced quality of life and reduced survival.²



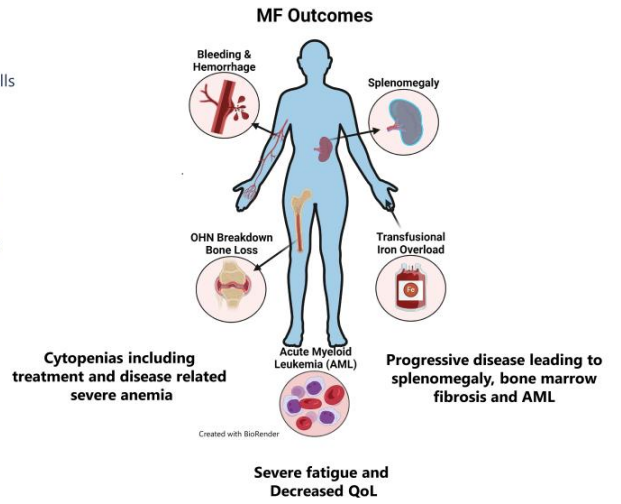
Current Treatments

Currently, there are limited therapeutic options to address the MF-associated cytopenias. Patients not only often experience multiple disease-associated, but also treatment-emergent, cytopenias, including anemia and thrombocytopenia



Scope

In the United States, there are 16,000 to 18,500 patients living with MF and approximately 3,000 newly diagnosed each year



1. Tefferi A, et al. Mayo Clin Proc. 2012; 2. Passamonti F, et al. Crit Rev Oncol Hematol. 2022

Ongoing Phase 2 Clinical Trial to Evaluate Elritercept as Monotherapy or in Combination with Ruxolitinib in Patients with MF



Primary MF, Post-ET or Post-PV MF with Anemia

Part 1: Dose Escalation
0.75 mg/kg to 4.5 mg/kg

Part 2: Dose Expansion
RP2D

Monotherapy:
JAK inhibitor relapsed, refractory, intolerant or ineligible

Monotherapy:
JAK inhibitor relapsed, refractory, intolerant or ineligible

Combination with Ruxolitinib:
Prior ruxolitinib treatment \geq 8 weeks with stable dose \geq 4 weeks

Combination with Ruxolitinib:
Prior ruxolitinib treatment \geq 8 weeks with stable dose \geq 4 weeks

Key Eligibility	Objectives and Endpoints	Trial Status
<ul style="list-style-type: none"> Transfusion dependent (TD): average of \geq6 RBC units/12 weeks with \geq1 transfusion within 28 days prior to treatment Non-transfusion dependent (Non-TD): baseline hemoglobin $<$ 10 g/dL, with or without transfusions Baseline platelet count \geq $25 \times 10^9/L$ 	<ul style="list-style-type: none"> Primary: To evaluate safety and tolerability of elritercept as monotherapy or in combination with ruxolitinib in patients with MF Secondary/Exploratory: To evaluate effects of elritercept with or without ruxolitinib on: <ul style="list-style-type: none"> Anemia, spleen volume, symptom score, exploratory biomarkers 	<ul style="list-style-type: none"> Data presented as of a data cut-off date of April 3, 2024 Dose escalation complete RP2D identified as 3.75 mg/kg with option to up-titrate to 5 mg/kg Q4W Part 2 Dose Expansion open and enrolling Total of 54 patients enrolled

Post-ET = post-essential thrombocythemia; Post-PV= post polycythemia vera



Trial Enrolled a Population with High Disease Burden

Parameter	Monotherapy (N=23)	Combination (N=31)	Total (N=54)
Age, years, median (range)	71.0 (60 - 85)	72.0 (45 - 86)	72.0 (45 - 86)
Male (%)	16 (69.6)	18 (58.1)	34 (63.0)
DIPSS risk, n (%)			
Intermediate - 1	4 (17.4)	2 (6.5)	6 (11.1)
Intermediate-2	14 (60.9)	18 (58.1)	32 (59.3)
High	5 (21.7)	11 (35.5)	16 (29.6)
Mutation, n (%)			
JAK2	12 (52.2)	18 (58.1)	30 (55.6)
CALR	2 (8.7)	7 (22.6)	9 (16.7)
MPL	4 (17.4)	2 (6.5)	6 (11.1)
Triple-negative	3 (13.0)	0	3 (5.6)
Prior JAK Inhibitor, n (%)	10 (43.5)	31 (100)	41 (75.9)
Transfusion Status			
TD*, n (%)	7 (30)	10 (32)	17 (31)
RBC U/12 wks, median (range)	10 (6 - 25)	10 (6 - 15)	10 (6 - 25)
Non-TD*, n (%)	16 (70)	21 (68)	37 (69)
RBC U/12 wks, median (range)	2 (0 - 9)	3 (0 - 5)	3 (0 - 9)
Hgb (g/dL), median (range)	8.18 (7.2 - 10.1)	8.08 (5.8 - 9.4)	8.10 (5.4 - 10.1)
Platelets, $\times 10^9/L$, median (range)	112.0 (27 - 561)	139.0 (42 - 311)	128.2 (27 - 561)
$< 150 \times 10^9/L$, n (%)	14 (60.6)	18 (58.1)	32 (59.3)
$< 50 \times 10^9/L$, n (%)	9 (39.1)	3 (9.7)	12 (22.2)
Received platelet transfusions, n (%)	5 (21.8)	0	5 (9.3)
Spleen volume, cm^3 , median (range)	968.4 (138 - 2650)	920.6 (270 - 6962)	937.4 (138 - 6962)
$\geq 450 cm^3$, n(%)**	16 (76.2)	19 (76)	35 (76.1)
Missing	2 (8.7)	6 (19.4)	8 (14.8)
MF-SAF-TSS, total, median (range)	16 (0 - 56)	12 (0 - 55)	14 (0 - 56)
≥ 10 , n(%)	20 (87.0)	21 (67.7)	41 (75.9)

Anemic Population
Heavily transfused population with 67% of participants receiving ≥ 3 RBC U/12 wks

Thrombocytopenia
More severe thrombocytopenia in monotherapy arm

Splenomegaly
76% evaluable for spleen response (spleen volume $\geq 450 cm^3$), including participants receiving ruxolitinib

Symptomatic
76% evaluable for symptom response (based on total MF-SAF-TSS ≥ 10 ***), including participants receiving ruxolitinib

Data are presented as of a data cut-off date of April 3, 2024.

CALR = calreticulin; DIPSS = dynamic international prognostic scoring system; JAK2 = Janus kinase 2; MPL = myeloproliferative leukemia protein gene; MF-SAF-TSS = myelofibrosis-symptom assessment form- total symptom score (version 4.0, 7-item)
 *Transfusion dependent is based on IWG 2013 criteria (Tefferi et al. Blood. 2013) and is defined as receiving ≥ 6 RBC units in the 12 weeks prior to first dose with at least one transfusion event in the 4 weeks preceding first dose **Percentage based on participants with non-missing baseline value ***3 additional participants (1 monotherapy, 2 combination) met criteria for being symptom response evaluable based on having at least two symptoms with an average score ≥ 3 .



Elritercept Was Generally Well-Tolerated in Patients with Significant Disease Burden

- **Most frequent TEAEs ($\geq 15\%$ of patients in both arms) regardless of causality:**
 - Thrombocytopenia (10, 18.5%)
 - Monotherapy: 7, 30.4%
 - Combination: 3, 9.7%
 - Diarrhea (9, 16.7%)
 - Monotherapy: 3, 13%
 - Combination: 6, 19.4%
- **In Part 1 Dose Escalation, 1 patient (monotherapy arm, 1.5 mg/kg dose) experienced a dose limiting toxicity (DLT) of hemoglobin increase ≥ 2 g/dL, which met protocol criteria for dose reduction and was not associated with AEs**
- **3 patients experienced Grade ≥ 3 TEAEs considered to be related to elritercept by the investigator**
 - Platelet count decreased
 - Hypertension
 - Thrombocytopenia
- **Four TEAEs leading to death, all deemed unrelated to study therapy**
 - Pneumonia aspiration
 - Multiple organ dysfunction
 - Transformation to AML
 - Cerebrovascular accident






Category, n (%)	Monotherapy (N=23)	Combination (N=31)	Total (N=54)
Exposure			
Median Duration, weeks (range)	24.1 (6-120)	23.7 (0-82)	23.9 (0-120)
Ongoing, n (%)	10 (43.5)*	21 (67.7)*	31 (57.4)*
Median Ruxolitinib Dose on C1D1, mg/day (range)	N/A	20 (10-50)	
Safety			
Any TEAE	23 (100)	25 (80.6)	48 (88.9)
TESAEs	10 (43.5)	11 (35.5)	21 (38.9)
Elritercept-Related TEAE	8 (34.8)	11 (35.5)	19 (35.2)
Ruxolitinib-Related TEAE	N/A	9 (29.0)	9 (16.7)
Elritercept-Related TEAE of Gr ≥ 3	0	3 (9.7)	3 (5.6)
Ruxolitinib-Related TEAE of Gr ≥ 3	N/A	0	0
TEAE Leading to Elritercept Discontinuation	6 (26.1)	3 (9.7)	9 (16.7)
TEAE Leading to Ruxolitinib Discontinuation	N/A	2 (6.5)	2 (3.7)
TEAE Leading to Death	2 (8.7)	2 (6.5)	4 (7.4)

Data are presented as of a data cut-off date of April 3, 2024

*As of the data cut-off date, 12/13 (92%) of Part 2 patients were ongoing, median exposure of 7.5 and 7.1 weeks for monotherapy and combination arms, respectively



Data Support Potential for Elritercept to Address Multiple Aspects of MF

Hematopoiesis	Spleen Size	Symptoms
<ul style="list-style-type: none"> Observed increases in markers of erythropoiesis were generally greater at higher doses Increases in Hgb were observed in both monotherapy and combination arms Reductions in transfusion burden observed in both arms further support potential to address ruxolitinib associated anemia as well as anemia due to underlying MF. In evaluable* patients receiving 3mg/kg of elritercept or higher in combination with ruxolitinib 5/11 (45.5%) achieved TI Improvements in platelet count were observed in patients with baseline thrombocytopenia particularly those treated with elritercept plus ruxolitinib 	<ul style="list-style-type: none"> 9/17 (53%) evaluable patients (2/8 mono, 7/9 combo) showed some reduction in spleen size at Week 24 Evaluable patients had baseline spleen size ≥ 450 cm³ and a Week 24 spleen volume assessment 3/9 (33%) had reductions $\geq 35\%$ Among the 7 evaluable patients in the combination arm who showed reductions in spleen size at Week 24, 6 occurred without ruxolitinib dose increase. 	<ul style="list-style-type: none"> Some reduction in symptom score observed in 13/20 (65%) evaluable patients at Week 24 Evaluable patients had MF-SAF-TSS ≥ 10 or had at least 2 symptoms with an average score \geq at baseline and a week 24 assessment 3 patients had reductions $\geq 50\%$ including 2 in monotherapy and 1 in combination arm
 	 	

Data are presented as of a data cut-off date of April 3, 2024.
 *Patients were included in the analysis if they received ≥ 3 RBC U/12 weeks at baseline;



Summary of Elritercept in Myelofibrosis

- The ongoing Phase 2 RESTORE trial of elritercept in MF has **enrolled a broad population of patients with high disease burden**
- Elritercept was **generally well-tolerated** in patients with MF, both as monotherapy and in combination with ruxolitinib
- Potential for elritercept to **address ineffective hematopoiesis in MF** is supported by observed **increases in hemoglobin, reduction in transfusion, and preservation or improvement of platelet counts**
- Observed effects on spleen volume reduction support potential for **elritercept to improve splenomegaly**, particularly in combination with ruxolitinib
- Potential for elritercept to **improve symptoms** is supported by observed reductions in total symptom score
- Enrollment in Part 2 of RESTORE trial is **ongoing at the RP2D of 3.75 mg/kg** with titration to 5 mg/kg to further study effects of elritercept in participants with MF

Improvements in hemoglobin, transfusion burden, spleen volume, and total symptom scores were observed in both monotherapy and combination arms, including at dose levels below the RP2D, supporting potential for elritercept to provide clinically meaningful benefits to patients with MF



Cibotercept (KER-012)

Investigational Treatment for Pulmonary Arterial Hypertension (PAH) and for Cardiovascular Disorders

Ongoing Phase 2, Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of KER-012 in Combination with Background Therapy in Adult Participants with Pulmonary Hypertension

Cibotercept (KER-012)

- Cibotercept is a **modified** activin receptor IIB ligand trap designed to **preferentially inhibit select ligands** to potentially rebalance TGF- β superfamily signaling **without a dose-limiting increase in RBCs**
- Completed a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of cibotercept in healthy volunteers
 - **No clinically meaningful changes in Hgb / RBCs observed** ^{1,2}
 - We believe PD data support potential for **maximal target engagement with doses being evaluated in the ongoing Phase 2 clinical trial (TROPOS)** ^{1,2}
- Ongoing TROPOS trial is a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial to evaluate KER-012 in combination with background therapy in adult patients with PAH
- **Expect to complete enrollment in Q4 2024**

Ciboterecept (KER-012) Open Label Biomarker Phase 2 Clinical Trial

- As part of its ongoing portfolio management activities, Keros has decided to **early terminate** its open-label Phase 2 biomarker clinical trial of ciboterecept in patients with chronic heart failure with preserved ejection fraction (HFpEF) and in such patients with reduced ejection fraction (HFrEF)
- **To date, we have not enrolled any patients in this trial**
- **The planned early termination is not on the basis of any safety concerns**



KER-065: *Obesity*

- ▶ We believe preclinical data suggests KER-065 has the potential to improve body composition by increasing muscle mass and decreasing fat mass alone or in combination with glucagon-like peptide-1 (GLP-1) receptor agonists
- ▶ By targeting activin A, KER-065 has the potential to directly reduce inflammation and fibrosis, the processes resulting in the development of cardiometabolic diseases
- ▶ Potential for infrequent subcutaneous dosing

KER-065

- KER-065 is a **novel ligand trap** designed to bind to and inhibit TGF- β ligands, **including myostatin (GDF8)** and **activin A**
- **Currently being evaluated in an ongoing Phase 1 clinical trial in healthy volunteers**
 - Primary Objectives: to **evaluate safety, tolerability and pharmacokinetics** of single and multiple ascending doses of KER-065
 - Exploratory Objectives: assess the pharmacodynamic effect on bone, adipose tissue, muscle, cardiac tissue and fibrosis
- Trial Subjects:
 - Healthy volunteers (males 18-55 years of age)
 - Body Mass Index:
 - SAD: 18.5 – 30
 - **MAD: 27 – 33**
- Based on the Safety Review Committee's recommendation, we have initiated the third dose cohort in the SAD portion at 5 mg/kg and have begun dosing the first MAD cohort of this trial at 2 mg/kg every four weeks. We continue to expect to report initial data from this trial in the first quarter of 2025

We believe this trial has the potential to provide biologic proof-of-concept to support initiation of a Phase 2 proof-of-concept clinical trial in patients with obesity



Anticipated Key Milestones

KER-050

- Announce additional data from Part 2 of Phase 2 MDS trial Q4 2024
- Announce additional data from Phase 2 MF trial Q4 2024

KER-012

- Complete enrollment in Phase 2 TROPOS Trial Q4 2024

KER-065

- Announce data from Phase 1 healthy volunteer trial Q1 2025





Q&A



