
**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 22, 2021

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.)

99 Hayden Avenue, Suite 120, Building E
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 7.01 Regulation FD Disclosure.

On June 22, 2021, Keros Therapeutics, Inc. (the "Company") updated its corporate presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 to this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and 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. The information contained in Item 7.01 to this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On June 22, 2021, the Company issued a press release announcing preliminary results from Cohorts 1 and 2 of its Phase 2 open-label clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in patients with very low-, low-, or intermediate-risk myelodysplastic syndromes ("MDS"). A copy of the press release is attached as Exhibit 99.2 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 23, 2021, the Company's management will discuss the preliminary results from its Phase 2 clinical trial of KER-050 in patients with MDS. A copy of the presentation for the conference call and webcast is attached as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation dated June 2021.
99.2	Press release dated June 22, 2021.
99.3	Investor Presentation dated June 2021.

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 22, 2021



Corporate Presentation

June 2021

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 and timing of its preclinical studies and clinical trials for KER-050, KER-047 and KER-012; the potential impact of COVID-19 on Keros' ongoing and planned preclinical studies, clinical trials, business and operations; and the potential of Keros' proprietary discovery approach. 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 lead product candidates, KER-050 and KER-047; 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; Keros' dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

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 6, 2021, 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.



Harnessing the Powerful Biology of the TGF- β Superfamily

- Clinical-stage biopharmaceutical company developing novel therapeutics that target the TGF- β superfamily
- Approach validated by marketed products, Infuse™ (BMP2) for spinal fusion and Reblozyl® (modified activin receptor IIB) for treatment of anemia in β -thalassemia and myelodysplastic syndromes (MDS)
- Leveraging our extensive experience in TGF- β superfamily protein structure, function and protein engineering to generate a clinical pipeline of differentiated therapeutics:

Hematology

KER-050: Modified activin receptor IIA (ActRIIA) ligand trap

- Designed to address ineffective hematopoiesis by modulating TGF- β superfamily signaling
- Potential to correct multiple cytopenias in patients with MDS and myelofibrosis (MF)

KER-047: Activin receptor-like kinase-2 (ALK2) inhibitor

- Designed to address anemias resulting from iron imbalance
- Potential to treat iron-refractory iron deficiency anemia (IRIDA), iron deficiency anemia and other diseases

Pulmonary and Musculoskeletal

KER-012: Modified activin receptor IIB ligand trap

- Designed to inhibit vascular remodeling and bone loss
- Potential to treat pulmonary arterial hypertension (PAH) and bone loss in osteogenesis imperfecta and osteoporosis



Keros is Developing Differentiated Clinical Assets in Hematological and Musculoskeletal Disorders

Program	Asset	Phase of Development				Status	Next Milestones*
		Preclinical	Phase 1	Phase 2	Phase 3		
Hematology	KER-050 (therapeutic protein)	Myelodysplastic syndromes (MDS)				Phase 2 clinical trial ongoing	Announce additional data from Part 1 of Phase 2 clinical trial: end of 2021
		Myelofibrosis				Completed Phase 1 clinical trial in healthy volunteers	Initiate Phase 2 clinical trial: Q3 2021 Initial data: 2022
	KER-047 (small molecule)	Iron deficiency anemia				Completed expanded Phase 1 clinical trial in healthy volunteers	Initiate Phase 2 clinical trial: H2 2021 Initial data: 2022
		Anemia from high hepcidin					Initiate Phase 2 clinical trial: H2 2021 Initial data: 2022
Musculoskeletal		Fibrodysplasia ossificans progressiva (FOP)					
Pulmonary	KER-012 (therapeutic protein)	Bone disorders				Ongoing preclinical studies	Initiate Phase 1 clinical trial: H2 2021 Initial data: H1 2022
		Pulmonary arterial hypertension					
Preclinical Pipeline		Musculoskeletal and hematology					



* Anticipated clinical milestones are subject to the impact of COVID-19 on our business.



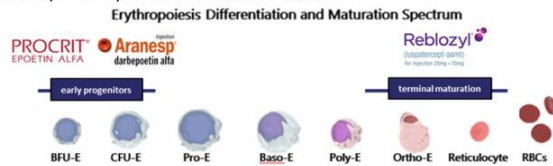
KER-050

A novel treatment designed to address diseases arising from ineffective hematopoiesis

- Myelodysplastic syndromes
- Myelofibrosis

Myelodysplastic Syndromes (MDS) Overview

- Hematologic malignancy predominantly affecting the elderly, resulting in multiple cytopenias (anemia, thrombocytopenia, neutropenia) due to ineffective hematopoiesis
 - 60,000-170,000 MDS patients in U.S.*
 - 15,000-20,000 newly diagnosed MDS patients in U.S. each year*
- 90% of patients are anemic and 40-65% have thrombocytopenia
- Platelet transfusion is the current treatment option for thrombocytopenia
- Anemia treatments include red blood cell (RBC) transfusions, erythropoiesis-stimulating agents (ESAs) and Reblozyl®
 - ESAs only impact early progenitors in red blood cell lineage and benefit is limited to patients with low transfusion burden and low endogenous EPO levels
 - Reblozyl® approved for treatment of anemia failing ESA in RS positive patients requiring transfusions
 - Approximately 15% of all MDS patients are RS positive and have defects in terminal maturation
 - 38% responders vs 13% placebo
 - Similar to ESAs, benefit primarily in low transfusion burden



*MDS Foundation

Myelofibrosis (MF) is Characterized by Ineffective Hematopoiesis

- Molecular abnormalities in JAK-STAT pathway result in expansion of RBC and platelet precursors and subsequent ineffective hematopoiesis
- Megakaryocyte accumulation/breakdown is implicated in the inducement of bone marrow fibrosis
- Plan to initiate a Phase 2 trial in MF in Q3 2021, evaluating effect on platelets and RBCs
 - We believe that KER-050 has the potential to address ineffective hematopoiesis, which is central to MF

16,000-18,500

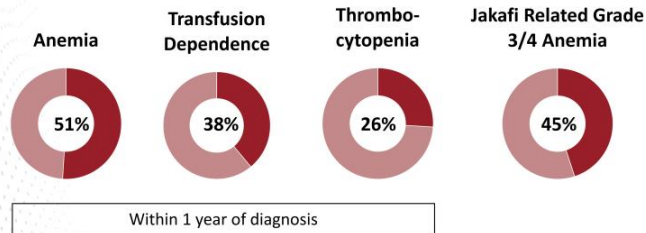
Prevalence of MF patients in US*

>3,000

New MF patients diagnosed each year**

~100 %

Nearly all MF patients will become transfusion-dependent***



*Gangat 2011; **Srouf 2016; ***Naymagon 2017

KER-050 is a Modified ActRII Fusion Protein

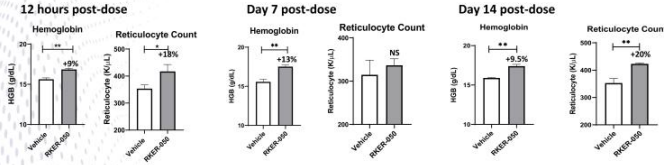
- Activin receptors are expressed on hematopoietic cells and modulate differentiation of precursor cells
- KER-050 is a ligand trap composed of a modified extracellular domain of activin receptor IIA (ActRIIA) fused to the Fc region of human IgG
- KER-050 is designed to increase RBC and platelet production by inhibiting the signaling of ligands through activin receptors
- Preclinical data demonstrate that increased RBCs by potentially increasing differentiation through multiple stages of erythropoiesis
 - Observed increases in platelets also potentially supports action throughout the thrombopoiesis pathway
- Phase 1 clinical trial of KER-050 recapitulated preclinical data with observed rapid, sustained and dose-dependent increases in RBCs and platelets



Treatment with RKER-050 Increased Erythropoiesis by Potentially Promoting Maturation at Multiple Stages and Increased Serum Erythropoietin

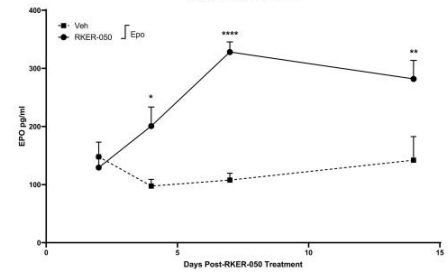
- In a preclinical study conducted in mice, a single, subcutaneous 10 mg/kg dose of a mouse version of KER-050 (RKER-050) resulted in:
 - Rapid increase in RBCs
 - Sustained increase continuing to at least 14 days post-dose
 - 2-3-fold increase in circulating erythropoietin
- KER-050 potentially acts on multiple stages across the RBC differentiation spectrum, including common myeloid cells

Increase in Red Blood Cells and Reticulocytes in Mice



*pv<0.05; **pv<0.01; ****pv<0.0001

Observed Increase in Serum Erythropoietin in Mice



* P value ≤0.05; ** P value ≤0.01; **** P value ≤0.0001

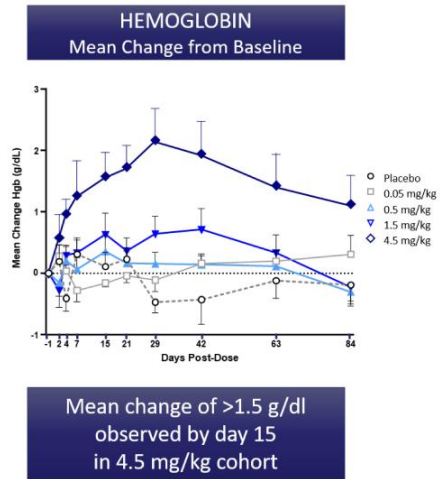
KER-050 Completed First-in-Human Trial

- First-in-human trial was designed to explore the safety, tolerability and PK in healthy volunteers with a secondary objective to evaluate changes in PD (hematology and bone biomarkers)
- Observed that KER-050 drug levels were dose proportional in Part 1 of the KER-050 Phase 1 clinical trial, with a mean half-life of approximately 12 days
 - The half-life coupled with the pharmacodynamic effect observed in the hematologic parameters support the potential for administration of monthly or less frequent dosing
- Observed to be well tolerated at dose levels up to 4.5 mg/kg, the highest dose level tested
- The most common adverse events observed in subjects in this trial were nausea, gastroenteritis, injection site erythema and, consistent with the mechanism of action of KER-050, increased hemoglobin and hypertension
 - Reversible, mild hypertension events observed in subjects with approximately 3 g/dL increase in hemoglobin



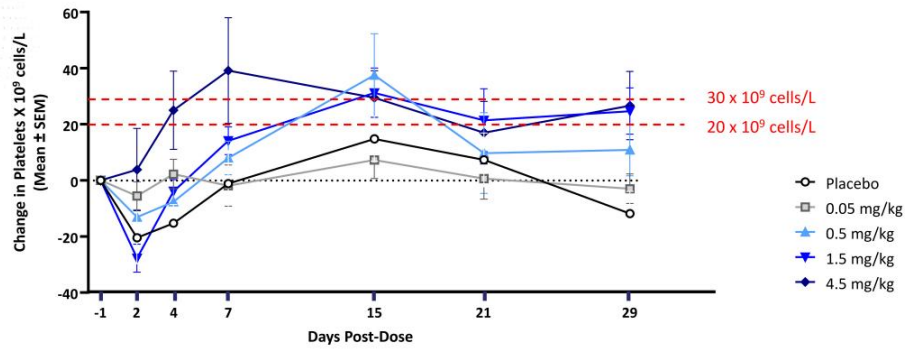
KER-050 Phase 1 Clinical Trial Recapitulated Learnings from Preclinical Studies

- Single, subcutaneous administration of KER-050 in healthy volunteers
- Observed rapid increase in red blood cell parameters is supportive of acceleration of maturation of late-stage precursors
 - Reticulocytes, red blood cells and hemoglobin
- Observed sustained increase from single dose supports monthly or less frequent dosing
 - Increases in RBC observed through day 29 are supportive of KER-050 acting on multiple stages of erythropoiesis
 - Maximum drug levels were observed on day 4



KER-050 Treatment was Observed to Lead to Clinically Meaningful Changes in Platelets after a Single Dose

Mean Change from Baseline in Platelets at Each Dose



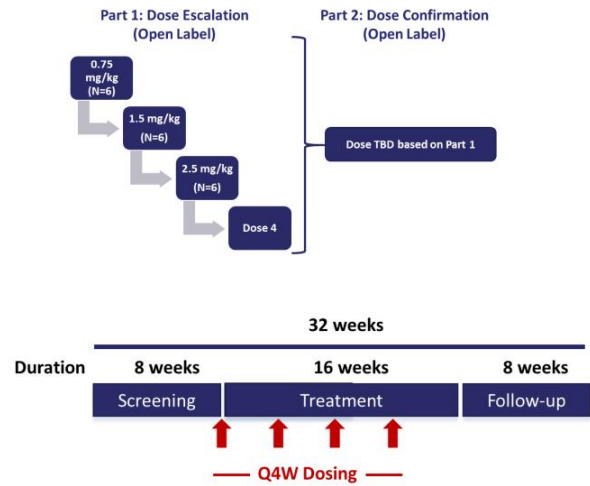


KER050-MD-201

**A Phase 2 Clinical Trial Of KER-050 For The
Treatment Of Anemia In Patients With
Very Low, Low Or Intermediate
Risk Myelodysplastic Syndromes (MDS)**

Phase 2 Clinical Trial of KER-050 in MDS

- Phase 2, multicenter, open-label clinical trial in very low-, low- and intermediate-risk MDS patients
- KER-050 administered once every four weeks (Q4W) for 12 weeks
- Trial objectives:
 - Safety, tolerability and pharmacokinetics
 - Evaluate pharmacodynamic effects and efficacy of KER-050
- Trial designed to evaluate KER-050 effects on hematopoiesis in:
 - Ring sideroblast (RS) positive and non-RS patients
 - ESA naïve and experienced
 - In high and low transfusion burden and non-transfused patients



Phase 2 Clinical Trial of KER-050 in MDS

Key Eligibility Criteria:

- MDS with very low-, low-, or intermediate-risk disease, as classified by the International Prognostic Scoring System-Revised, including both RS positive and non-RS
- ESA naïve and experienced patients are eligible
- No prior treatment with azacitidine, decitabine, lenalidomide, luspatercept or sotatercept
- Anemia, categorized in one of the following three groups:
 - Non-transfused (NT): hemoglobin (Hgb) <10 g/dL
 - Low transfusion burden (LTB): 1-3 units of RBC/8 weeks, Hgb <10 g/dL
 - High transfusion burden (HTB): ≥4 units of RBC/8 weeks

Select Efficacy Endpoints:

- Hemoglobin increase of ≥1.5 g/ dL for 8 weeks (in NT and LTB patients)
- Reduction of ≥4 units or ≥50% units transfused over 8 weeks compared to baseline (in HTB patients)
- Transfusion independence for at least 8 weeks (in LTB and HTB patients)



Trial Status and Baseline Characteristics

- Data cut-off date: May 14, 2021
- Preliminary data presented from two lowest dose cohorts:
 - Cohort 1: 0.75 mg/kg Q4W for 12 weeks
 - Cohort 2: 1.5 mg/kg Q4W for 12 weeks
- 12 patients received at least one dose of KER-050 as of the data cut-off date
 - 9 patients completed 8 weeks of treatment with KER-050 as of the data cut-off date
 - 2 patients withdrew from the trial prior to completing 8 weeks of treatment with KER-050
 - 1 patient had not completed 8 weeks of treatment with KER-050 as of the data cut-off date
- Baseline characteristics (n=12):
 - 50% RS positive and non-RS
 - 50% had erythropoietin >100 mIU/mL
 - 50% HTB (≥ 4 units/8 weeks)
 - 85% had multilineage dysplasia
 - Mean platelet count of $192.4 \times 10^9/L$



Safety Profile as of May 14, 2021

- Safety Review Committee has reviewed preliminary 0.75 mg/kg (Cohort 1) and 1.5 mg/kg (Cohort 2) data
- Summary of safety profile* (Cohorts 1 and 2; n=12):
 - No drug related serious adverse events (SAEs)
 - 4 treatment-emergent SAEs deemed unrelated to study drug (anemia, febrile illness, pneumonia and death)
 - 1 treatment-related adverse event of maculopapular rash (Grade 2)
 - 2 withdrawals (death deemed unrelated to study drug; patient decision)
- Cohort 3 (2.5 mg/kg Q4W) has been initiated following Safety Review Committee recommendation



*Data cut-off date: May 14, 2021

Preliminary Results from Phase 2 Clinical Trial

Preliminary results*:

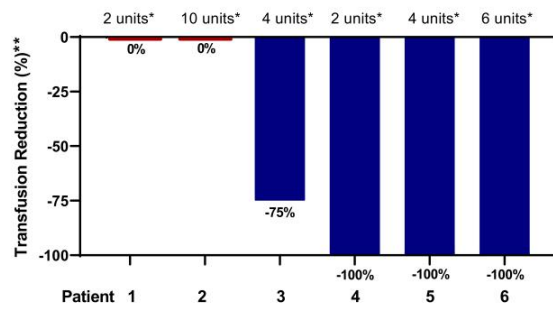
- Consistent with the data from the Phase 1 clinical trial, increases in reticulocytes, Hgb and platelets were observed in MDS patients
- 5 patients that completed 8 weeks of treatment with KER-050 as of the data cut-off date met at least one of the following three endpoints:
 - Increase in hemoglobin ≥ 1.5 g/dL for 8 weeks, or
 - 50% reduction in transfusion requirements over 8 weeks, or
 - Transfusion independence for at least 8 weeks
- 3 patients achieved transfusion independence ≥ 8 weeks in duration
- Reduction in transfusions observed in both RS positive and non-RS patients

*Data cut-off date: May 14, 2021



Reduction in Transfusion Burden Observed⁺

- Patients requiring transfusions at baseline (≥ 2 RBC units/8 weeks) that completed 8 weeks of treatment with KER-050 as of the data cut-off date were evaluated for transfusion reduction
 - 6 patients required transfusion at baseline (2-10 RBC units over 8 weeks)
- Clinically meaningful reductions in transfusion burden as well as transfusion independence were observed with Q4W dosing schedule



⁺Data cut-off date: May 14, 2021

^{*}Baseline transfusion burden over 8 weeks

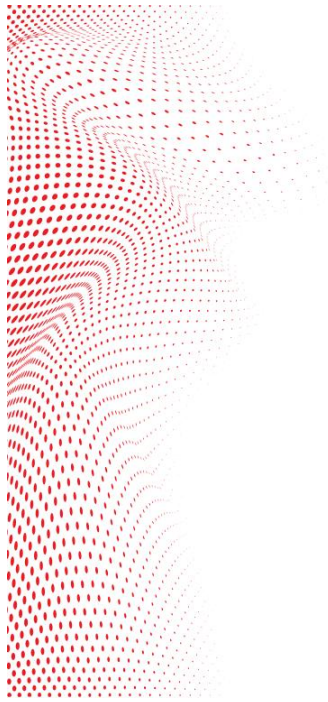
^{**}Percent transfusion reduction over 8 weeks on treatment compared to baseline transfusion burden



Summary of KER-050 Phase 2 Clinical Trial

- Keros believes the initial preliminary data from this 12-week treatment Phase 2 clinical trial demonstrate proof-of-concept of KER-050 in patients with very low-, low- or intermediate-risk MDS
 - Data consistent with observations from the Phase 1 clinical trial in healthy volunteers
- Increases in hematological parameters were observed in RS positive and non-RS patients that received doses of KER-050 Q4W
 - Increases in reticulocytes, hemoglobin and platelets were observed
- Clinically meaningful reductions in transfusion burden as well as transfusion independence were observed
- Lowest two doses were well tolerated as of the data cut-off date
- Cohort 3 dosing at 2.5 mg/kg Q4W has been initiated
- Keros plans to:
 - Update protocol to increase size of Part 2 (dose confirmation) to confirm response rates and guide design of registration program
 - Extend treatment duration from 12 weeks to up to 2 years to define response rate following 6 months of treatment, confirm durability of response and guide design of registration program
 - Share additional Part 1 dose-escalation data and Part 2 trial design by the end of 2021





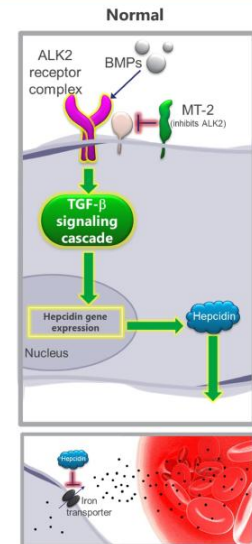
KER-047

A novel treatment designed to address:

- Anemia resulting from iron imbalance
 - Iron deficiency anemia
 - IRIDA
- Fibrodysplasia ossificans progressiva (FOP)

ALK2 Regulates Hepcidin and Iron Homeostasis

- ALK2 signaling in the liver controls hepcidin expression, a hormone that controls iron homeostasis
- Excessive ALK2 signaling results in high hepcidin and a shortage of iron availability for RBC production
- ALK2 signaling requires BMP ligand and the co-receptor hemojuvelin
- Hepcidin expression is tightly regulated and controls expression of the ALK2 suppressor protease MT-2
 - The genetic disease iron-refractory iron deficiency anemia (IRIDA) is characterized by loss of MT-2
 - High hepcidin has also been implicated in anemia of inflammation
- Modulating ALK2 signaling will normalize high hepcidin levels, restore serum iron and ameliorate anemia



Inhibition of ALK2 Demonstrated Activity in Rodent Models of Iron Imbalance

- ALK2 inhibition decreased hepcidin and increased serum iron in mice
- In a mouse model of IRIDA, treatment with ALK2 inhibitors reduced hepcidin and ameliorated anemia
- In a mouse model of chronic kidney disease, chronic inflammation resulted in increased hepcidin, reduced serum iron and anemia
 - Treatment with an ALK2 inhibitor reduced hepcidin, increased serum iron and resolved anemia
- Frequent infusions of red blood cells or iron (intravenous) results in iron overload in the liver, heart and other tissue
 - Treatment with an ALK2 inhibitor mobilized the iron and reduced iron deposits in the liver in mice

Inhibition of ALK2 has the potential to restore iron balance and treat patients with anemia and patients with iron overload

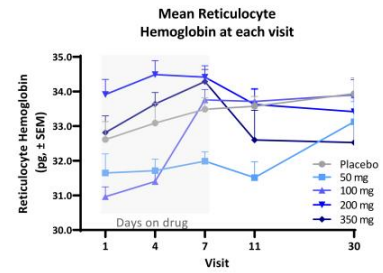
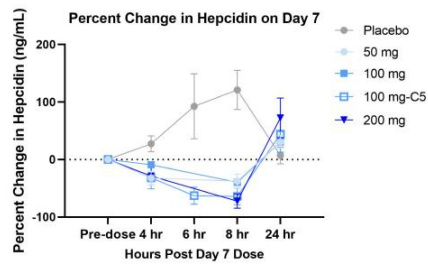


Phase 1 Clinical Trial of KER-047 in Healthy Volunteers

- KER-047 is a small molecule inhibitor of the ALK2 kinase domain with low nanomolar IC₅₀
- PK/ADME: Suitable for 1x daily oral dosing
- In November 2020, Keros completed a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-047 in healthy volunteers
- Primary objectives: Evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic effects of single and multiple ascending dose levels of KER-047 in healthy volunteers
- Tolerability Profile:
 - There were no serious adverse events reported in the KER-047 Phase 1 clinical trial
 - Most common adverse events observed: abdominal discomfort, chills, decreased appetite, diarrhea, dizziness, fatigue, gastroenteritis, headache, lymphopenia, myalgia, nausea, neutropenia, pyrexia, rhinorrhea, tonsilitis, upper abdominal pain and vomiting



Phase 1 Clinical Trial: KER-047 Treatment Led to Reduced Hepcidin Levels and Increased Hemoglobin Content in Reticulocytes



- Consistent with ALK2 inhibition, decreases in serum hepcidin were observed in Cohorts 1 through 3 of Part of the expanded trial
- An increase in reticulocyte hemoglobin was observed in Cohorts 1 through 4 of Part 2 of the expanded trial, starting on Day 4 of treatment
- Pronounced increase in reticulocyte hemoglobin observed in cohorts with lower baseline reticulocyte hemoglobin



Phase 2 Trials to Provide Proof-of-Concept for Treatment of Anemia Resulting from Iron Imbalance, Including IDA and IRIDA

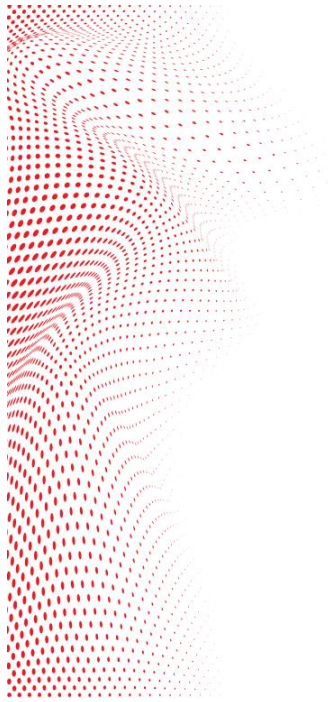
Iron Deficiency Anemia

- KER-047 is designed to re-establish normal iron homeostasis by mobilizing iron out of tissues, thereby ameliorating anemia
- We expect to initiate a Phase 2 clinical trial in patients with iron deficiency anemia in H2 2021 and expect to report initial data from this trial in 2022

IRIDA

- KER-047 is designed to normalize high hepcidin levels, restore serum iron and ameliorate anemia
- We expect to initiate a Phase 2 clinical trial in patients with IRIDA in H2 2021 and expect to report initial data from this trial in 2022





KER-012

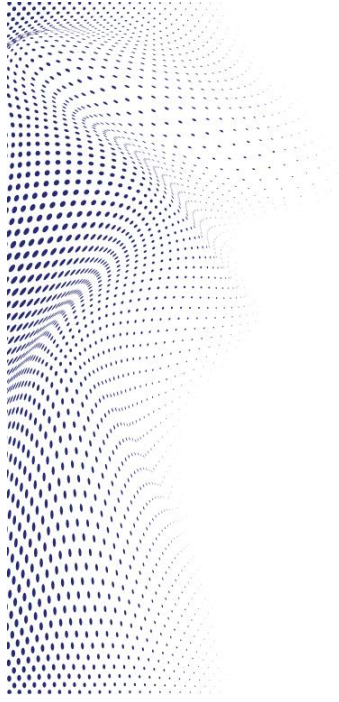
A preclinical program designed to address

- Bone loss disorders such as osteoporosis and osteogenesis imperfecta
- Pulmonary arterial hypertension (PAH)

KER-012: Preclinical Product Candidate

- Proprietary selective activin receptor ligand trap in preclinical development for the treatment of pulmonary arterial hypertension (PAH) and bone disorders
- In preclinical studies, KER-012:
 - Demonstrated high affinity for, and potent inhibition of, ligands involved in the regulation of bone homeostasis
 - Increased bone mineral density and trabecular bone volume in wild-type mice and mice with established osteoporosis
 - Did not increase red blood cell production in cynomolgus monkeys
- In a rat model of PAH, rats receiving a rodent version of KER-012 (RKER-012) were protected from the thickening of the right ventricular wall
 - In addition, rats receiving RKER-012 were protected from PAH-associated bone loss
- We believe KER-012 has the potential to increase the signaling of BMP pathways by inhibiting activin A and activin B signaling and, consequently, treat diseases such as PAH that are associated with reduced BMP signaling
- We expect to initiate a Phase 1 clinical trial in healthy volunteers in H2 2021





Keros Summary

We Believe Keros is Positioned for Clinical and Commercial Success

- Keros is focused on the development of novel TGF- β therapeutics
 - Robust biology that has been validated in the clinic
- Keros is well-positioned to harness the potential of the TGF- β superfamily
 - ActRII program (KER-050) is in a Phase 2 trial in patients with MDS and we expect to initiate a Phase 2 trial in patients with MF in Q3 2021
 - Multiple Phase 2 trials for ALK2 program (KER-047) expected to commence in H2 2021
 - KER-012 is a selective activin receptor ligand trap expected to enter a Phase 1 trial in H2 2021
 - Clinical programs have potentially differentiated mechanism of action
- Our discovery approach has the potential to identify additional molecules with differentiated profiles from existing third-party products and product candidates
 - Pipeline of preclinical assets: bone, muscle and pulmonary



Anticipated Key Milestones*

KER-050

- Announce additional data from Part 1 of Phase 2 trial in MDS
- Initiate Phase 2 trial in myelofibrosis

End of 2021
Q3 2021 (initial data 2022)

KER-047

- Initiate Phase 2 trial in IDA
- Initiate Phase 2 trial in IRIDA

H2 2021 (initial data 2022)
H2 2021 (initial data 2022)

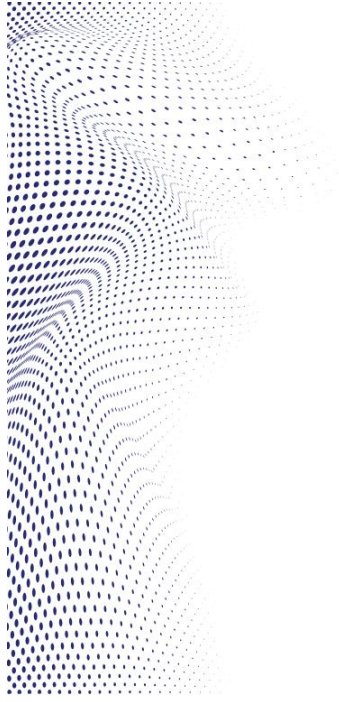
KER-012

- Present preclinical data on PAH at major conference
- Initiate Phase 1 trial in healthy volunteers

2021
H2 2021 (initial data H1 2022)



*Anticipated preclinical and clinical milestones are subject to the impact of COVID-19 on our business.



Thank You

Keros Therapeutics Announces Preliminary Results from its Phase 2 Clinical Trial Evaluating KER-050 in Patients with Myelodysplastic Syndromes

LEXINGTON, Mass., – June 22, 2021 – Keros Therapeutics, Inc. (“Keros”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need, today announced preliminary results from Cohorts 1 and 2 of its Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in patients with very low-, low-, or intermediate-risk myelodysplastic syndromes (“MDS”) who either have ring sideroblasts (“RS positive”) or do not have ring sideroblasts (“non-RS”) and who either have or have not previously received treatment with an erythroid stimulating agent.

The ongoing trial is designed as an open-label, two-part, multiple ascending dose trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of KER-050 in patients with MDS. As of May 14, 2021 (the “data cut-off date”), 12 patients had received at least one dose of KER-050, nine of whom had completed eight weeks of treatment. Patients in Cohort 1 and 2 received 0.75 mg/kg and 1.5 mg/kg doses of KER-050, respectively, once every four weeks for 12 weeks. Preliminary results from Cohorts 1 and 2 of the trial, as of the data cut-off date, include:

- Five patients that completed eight weeks of treatment with KER-050 as of the data cut-off date met at least one of the following endpoints:
 - Increase in hemoglobin \geq 1.5 g/dL for eight weeks, or
 - 50% reduction in transfusion requirements over eight weeks, or
 - Transfusion independence for at least eight weeks.
- Observed increases in reticulocytes, hemoglobin and platelets.
- Observed clinically meaningful reductions in transfusion burden in both RS positive and non-RS patients that required transfusions at baseline (\geq 2 red blood cell units over eight weeks).
- Three patients that completed eight weeks of treatment with KER-050 as of the data cut-off date achieved transfusion independence for at least eight weeks.

As of the data cut-off date, KER-050 was well tolerated in Cohorts 1 and 2 of this trial. No drug-related serious adverse events (“SAEs”) were reported. There were four treatment-emergent SAEs reported, all of which were deemed unrelated to study drug, including anemia, febrile illness, pneumonia and death. Two patients withdrew from the trial prior to completing eight weeks of treatment with KER-050, one due to death deemed unrelated to study drug and one patient withdrew consent. There was one observed treatment-related adverse event of maculopapular rash that was moderate in severity.

“These preliminary results are encouraging, as we observed increases in hematological parameters in the two lowest Part 1 dose cohorts, dosed monthly, in both RS positive and non-RS patients with MDS,” said Jasbir S. Sehra, Ph.D., Chief Executive Officer of Keros. “We believe these initial results demonstrate proof-of-concept of KER-050 in patients with very low-, low- to intermediate-risk MDS, and support the potential of KER-050 as a treatment for diseases associated with ineffective hematopoiesis.”

Following Safety Review Committee recommendation, dosing for Cohort 3 of the trial was initiated at 2.5 mg/kg of KER-050, to be administered once every four weeks for 12 weeks. Keros expects to report additional Part 1 data and initiate Part 2 of the trial by the end of 2021.

Additionally, based on these preliminary results as of the data cut-off date, Keros plans to extend the treatment duration of the trial from 12 weeks to up to two years to define response rate following six months of treatment with KER-050 and to confirm durability of response. Keros also intends to update the protocol to increase the size of Part 2 of the trial to confirm response rates and to help guide the

design of the expected registration program. Keros expects to share the Part 2 trial design by the end of 2021.

Conference Call and Webcast

Keros will host a conference call and webcast on Wednesday, June 23, 2021 at 8:00 AM EDT to review the preliminary results from the KER-050 Phase 2 clinical trial. The conference call will be webcast live at <https://edge.media-server.com/mmc/p/pnjzf86g>. The live teleconference may be accessed by dialing (833) 528-0563 (domestic) or (830) 221-9673 (international) and entering conference ID: 1889520. 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 KER-050

Keros' lead protein therapeutic product candidate, KER-050, is an engineered ligand trap comprised of a modified ligand-binding domain of the Transforming Growth Factor-Beta receptor known as activin receptor type IIA that is fused to the portion of the human antibody known as the Fc domain. KER-050 is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes, or MDS, and in patients with myelofibrosis.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematologic and musculoskeletal disorders with high unmet medical need. Keros is a leader in understanding the role of the Transforming Growth Factor-Beta family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. Keros' lead protein therapeutic product candidate, KER-050, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes and in patients with myelofibrosis. Keros' lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva. Keros' third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension.

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 "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 and timing of its clinical trials for KER-050; and the potential of KER-050 to treat patients with MDS and diseases associated with ineffective hematopoiesis. 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 lead product candidates, KER-050 and KER-047; 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; Keros' dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

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 6, 2021, 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:

Mike Biega
mbiega@soleburytrout.com
617-921-9660



KER-050 Update

23 June 2021

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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 we make 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.

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Keros Attendees

- Jasbir Seehra, Chief Executive Officer
- Claudia Ordonez, Chief Medical Officer
- Keith Regnante, Chief Financial Officer



Harnessing the Powerful Biology of the TGF- β Superfamily

- Clinical-stage biopharmaceutical company developing novel therapeutics that target the TGF- β superfamily
- Approach validated by marketed products, Infuse™ (BMP2) for spinal fusion and Reblozyl® (modified activin receptor IIB) for treatment of anemia in β -thalassemia and myelodysplastic syndromes
- Leveraging our extensive experience in TGF- β superfamily protein structure, function and protein engineering to generate a clinical pipeline of differentiated therapeutics:

Hematology

KER-050: Modified activin receptor IIA (ActRIIA) ligand trap

- Designed to address ineffective hematopoiesis by modulating TGF- β superfamily signaling
- Potential to correct multiple cytopenias in patients with MDS and myelofibrosis (MF)

KER-047: Activin receptor-like kinase-2 (ALK2) inhibitor

- Designed to address anemias resulting from iron imbalance
- Potential to treat iron-refractory iron deficiency anemia (IRIDA), iron deficiency anemia and other diseases

Pulmonary and Musculoskeletal

KER-012: Modified activin receptor IIB ligand trap

- Designed to inhibit vascular remodeling and bone loss
- Potential to treat pulmonary arterial hypertension (PAH) and bone loss in osteogenesis imperfecta and osteoporosis



Keros is Developing Differentiated Clinical Assets in Hematological and Musculoskeletal Disorders

Program	Asset	Phase of Development				Status	Next Milestones*
		Preclinical	Phase 1	Phase 2	Phase 3		
Hematology	KER-050 (therapeutic protein)	Myelodysplastic syndromes (MDS)				Phase 2 clinical trial ongoing	Announce additional data from Part 1 of Phase 2 clinical trial: end of 2021
		Myelofibrosis					
	KER-047 (small molecule)	Iron deficiency anemia				Completed Phase 1 clinical trial in healthy volunteers	Initiate Phase 2 clinical trial: Q3 2021 Initial data: 2022
		Anemia from high hepcidin					
Musculoskeletal		Fibrodysplasia ossificans progressiva (FOP)					Initiate Phase 2 clinical trial: H2 2021 Initial data: 2022
Pulmonary	KER-012 (therapeutic protein)	Bone disorders				Ongoing preclinical studies	Initiate Phase 1 clinical trial: H2 2021 Initial data: H1 2022
		Pulmonary arterial hypertension					
Preclinical Pipeline		Musculoskeletal and hematology					



* Anticipated clinical milestones are subject to the impact of COVID-19 on our business.



KER-050

A novel treatment designed to address diseases arising from ineffective hematopoiesis

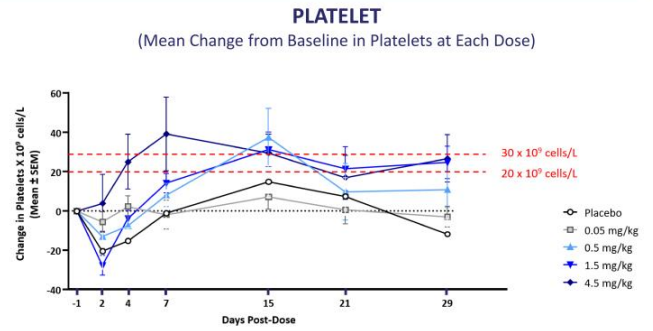
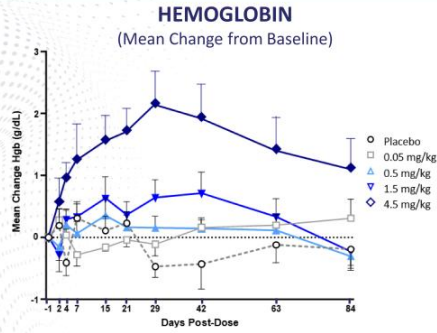
- Myelodysplastic syndromes
- Myelofibrosis

KER-050 is a Modified ActRII Fusion Protein

- Activin receptors are expressed on hematopoietic cells and modulate differentiation of precursor cells
- KER-050 is a ligand trap composed of a modified extracellular domain of ActRIIA fused to the Fc region of human IgG
- KER-050 is designed to increase red blood cell (RBC) and platelet production by inhibiting the signaling of ligands through activin receptors



KER-050 Increased RBC Parameters and Platelets following Single Doses in Phase 1 Clinical Trial in Healthy Volunteers



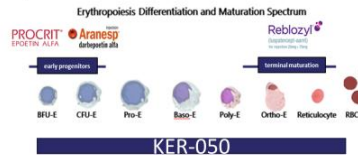
- Observed rapid and sustained increase in RBC parameters through day 29 are supportive of KER-050 acting on multiple stages of erythropoiesis
 - Reticulocytes, RBCs and hemoglobin
- Observed sustained increase from single dose supports monthly or less frequent dosing

- Single doses of KER-050 observed to lead to clinically meaningful changes in platelets
- Maximum changes observed 7-15 days post-dosing

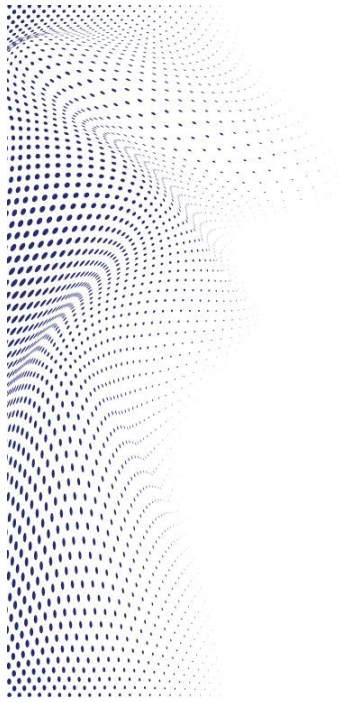


Myelodysplastic Syndromes (MDS) Overview

- Hematologic malignancy predominantly affecting the elderly, resulting in multiple cytopenias (anemia, thrombocytopenia, neutropenia) due to ineffective hematopoiesis
 - 60,000-170,000 MDS patients in U.S.*
 - 15,000-20,000 newly diagnosed MDS patients in U.S. each year*
- 90% of patients are anemic and 40-65% have thrombocytopenia
- Platelet transfusion is the current treatment option for thrombocytopenia
- Anemia treatments include RBC transfusions, erythropoiesis-stimulating agents (ESAs) and Reblozyl®
 - ESAs only impact early progenitors in RBC lineage and benefit is limited to patients with low transfusion burden and low endogenous erythropoietin (EPO) levels
 - Reblozyl® approved for treatment of anemia failing ESA in RS positive patients requiring transfusions
 - Approximately 15% of all MDS patients are RS positive and have defects in terminal maturation
 - 38% responders vs 13% placebo
 - Similar to ESAs, benefit primarily in low transfusion burden



*MDS Foundation

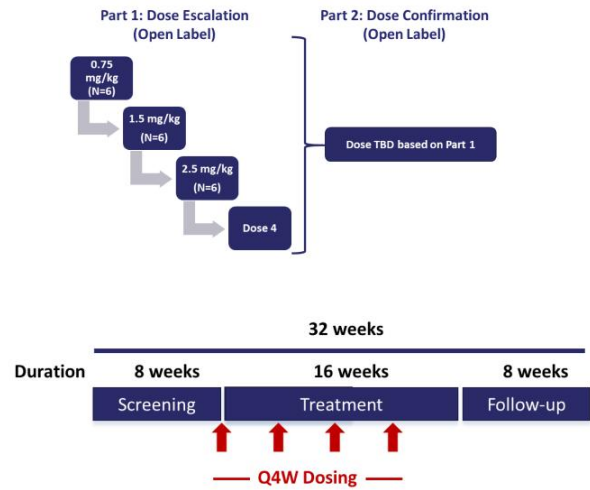


KER050-MD-201

A Phase 2 Clinical Trial Of KER-050 For The Treatment Of Anemia In Patients With Very Low, Low Or Intermediate Risk Myelodysplastic Syndromes (MDS)

Phase 2 Clinical Trial of KER-050 in MDS

- Phase 2, multicenter, open-label clinical trial in very low-, low- and intermediate-risk MDS patients
- KER-050 administered once every four weeks (Q4W) for 12 weeks
- Trial objectives:
 - Safety, tolerability and pharmacokinetics
 - Evaluate pharmacodynamic effects and efficacy of KER-050
- Trial designed to evaluate KER-050 effects on hematopoiesis in:
 - Ring sideroblast (RS) positive and non-RS patients
 - ESA naïve and experienced
 - In high and low transfusion burden and non-transfused patients



Phase 2 Clinical Trial of KER-050 in MDS

Key Eligibility Criteria:

- MDS with very low-, low-, or intermediate-risk disease, as classified by the International Prognostic Scoring System-Revised, including both RS positive and non-RS
- ESA naïve and experienced patients are eligible
- No prior treatment with azacitidine, decitabine, lenalidomide, luspatercept or sotatercept
- Anemia, categorized in one of the following three groups:
 - Non-transfused (NT): hemoglobin (Hgb) <10 g/dL
 - Low transfusion burden (LTB): 1-3 units of RBC/8 weeks, Hgb <10 g/dL
 - High transfusion burden (HTB): ≥4 units of RBC/8 weeks

Select Efficacy Endpoints:

- Hemoglobin increase of ≥1.5 g/dL for 8 weeks (in NT and LTB patients)
- Reduction of ≥4 units or ≥50% units transfused over 8 weeks compared to baseline (in HTB patients)
- Transfusion independence for at least 8 weeks (in LTB and HTB patients)



Trial Status and Baseline Characteristics

- Data cut-off date: May 14, 2021
- Preliminary data presented from two lowest dose cohorts:
 - Cohort 1: 0.75 mg/kg Q4W for 12 weeks
 - Cohort 2: 1.5 mg/kg Q4W for 12 weeks
- 12 patients received at least one dose of KER-050 as of the data cut-off date
 - 9 patients completed 8 weeks of treatment with KER-050 as of the data cut-off date
 - 2 patients withdrew from the trial prior to completing 8 weeks of treatment with KER-050
 - 1 patient had not completed 8 weeks of treatment with KER-050 as of the data cut-off date
- Baseline characteristics (n=12):
 - 50% RS positive and non-RS
 - 50% had erythropoietin >100 mIU/mL
 - 50% HTB (≥ 4 units/8 weeks)
 - 85% had multilineage dysplasia
 - Mean platelet count of $192.4 \times 10^9/L$



Safety Profile as of May 14, 2021

- Safety Review Committee has reviewed preliminary 0.75 mg/kg (Cohort 1) and 1.5 mg/kg (Cohort 2) data
- Summary of safety profile* (Cohorts 1 and 2; n=12):
 - No drug related serious adverse events (SAEs)
 - 4 treatment-emergent SAEs deemed unrelated to study drug (anemia, febrile illness, pneumonia and death)
 - 1 treatment-related adverse event of maculopapular rash (Grade 2)
 - 2 withdrawals (death deemed unrelated to study drug; patient decision)
- Cohort 3 (2.5 mg/kg Q4W) has been initiated following Safety Review Committee recommendation

*Data cut-off date: May 14, 2021

Preliminary Results

Preliminary results*:

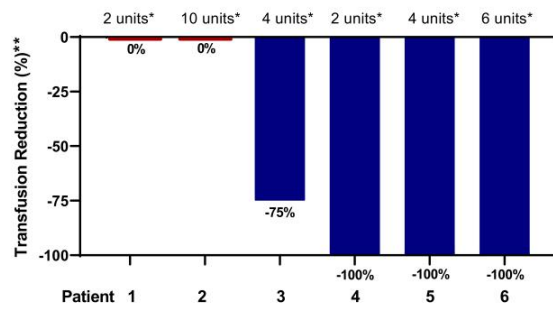
- Consistent with the data from the Phase 1 clinical trial, increases in reticulocytes, Hgb and platelets were observed in MDS patients
- 5 patients that completed 8 weeks of treatment with KER-050 as of the data cut-off date met at least one of the following three endpoints:
 - Increase in hemoglobin ≥ 1.5 g/dL for 8 weeks, or
 - 50% reduction in transfusion requirements over 8 weeks, or
 - Transfusion independence for at least 8 weeks
- 3 patients achieved transfusion independence ≥ 8 weeks in duration
- Reduction in transfusions observed in both RS positive and non-RS patients

*Data cut-off date: May 14, 2021



Reduction in Transfusion Burden Observed⁺

- Patients requiring transfusions at baseline (≥ 2 RBC units/8 weeks) that completed 8 weeks of treatment with KER-050 as of the data cut-off date were evaluated for transfusion reduction
 - 6 patients required transfusion at baseline (2-10 RBC units over 8 weeks)
- Clinically meaningful reductions in transfusion burden as well as transfusion independence were observed with Q4W dosing schedule



⁺Data cut-off date: May 14, 2021

*Baseline transfusion burden over 8 weeks

**Percent transfusion reduction over 8 weeks on treatment compared to baseline transfusion burden



KER-050 MDS Program Update

- Dosing has been initiated in Cohort 3 at 2.5 mg/kg Q4W following Safety Review Committee recommendation
- Keros expects to report additional Part 1 data and initiate Part 2 of the trial by the end of 2021
- Based on the preliminary results as of the data cut-off date (May 14, 2021), Keros plans to:
 - Extend treatment duration from 12 weeks to up to 2 years to define response rate following 6 months of treatment and to confirm durability of response
 - Update protocol to increase size of Part 2 dose confirmation to confirm response rates and guide design of registration program
- Keros plans to share the Part 2 trial design by the end of 2021



Summary

- Keros believes the initial preliminary data from this 12-week treatment Phase 2 clinical trial demonstrate proof-of-concept of KER-050 in patients with very low-, low- or intermediate-risk MDS
 - Data consistent with observations from the Phase 1 clinical trial in healthy volunteers
- Increases in hematological parameters were observed in RS positive and non-RS patients that received doses of KER-050 Q4W
 - Increases in reticulocytes, hemoglobin and platelets were observed
- Clinically meaningful reductions in transfusion burden as well as transfusion independence were observed
- Lowest two doses were well tolerated as of the data cut-off date
- Cohort 3 dosing at 2.5 mg/kg Q4W has been initiated
- Keros plans to:
 - Update protocol to increase size of Part 2 (dose confirmation) to confirm response rates and guide design of registration program
 - Extend treatment duration from 12 weeks to up to 2 years to define response rate following 6 months of treatment, confirm durability of response and guide design of registration program
 - Share additional Part 1 dose-escalation data and Part 2 trial design by the end of 2021



Anticipated Key Milestones*

KER-050

- Announce additional data from Part 1 of Phase 2 trial in MDS
- Initiate Phase 2 trial in myelofibrosis

End of 2021
Q3 2021 (initial data 2022)

KER-047

- Initiate Phase 2 trial in IDA
- Initiate Phase 2 trial in IRIDA

H2 2021 (initial data 2022)
H2 2021 (initial data 2022)

KER-012

- Present preclinical data on PAH at major conference
- Initiate Phase 1 trial in healthy volunteers

2021
H2 2021 (initial data H1 2022)



*Anticipated preclinical and clinical milestones are subject to the impact of COVID-19 on our business.

Q+A Session



