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

June 22, 2021 8:01 PM EDT

LEXINGTON, Mass., June 22, 2021 (GLOBE NEWSWIRE) -- 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 ≥ 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 (≥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. Seehra, 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
617-921-966