Keros Therapeutics, Inc. Announces Dosing of First Participants in Phase 2 Clinical Trial of KER-050 in Myelodysplastic Syndromes (MDS)

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- *First two participants dosed in a Phase 2 clinical trial of KER-050 in MDS*
- *Initial data expected by mid-2021*

LEXINGTON, Mass., Oct. 20, 2020 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. ("Keros" or the "Company") (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 that it has dosed the first two participants in a Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in myelodysplastic syndromes ("MDS"). Keros expects to report initial data from Part 1 of this trial in mid-2021.

The Phase 2 clinical trial is an open-label, multiple ascending dose trial to evaluate KER-050 in participants with very low-, low-, or intermediate-risk MDS who either have previously received treatment with an erythropoiesis-stimulating agent or have not received such treatment. Keros presented data from its Phase 1 clinical trial of KER-050 in healthy post-menopausal women, which demonstrated a robust, dose-dependent response of multiple hematological parameters, at the 25th Annual Congress of European Hematology Association in June 2020.

"We are pleased to announce the initiation of our open-label Phase 2 clinical trial of KER-050 in MDS. The results from our Phase 1 clinical trial demonstrated robust hematological effects in healthy volunteers that we are excited to potentially explore further in patients with MDS." said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. "The majority of patients with MDS develop anemias and other cytopenias and we believe that the differentiated mechanism of action of KER-050 provides a potential benefit not only in addressing ineffective erythropoiesis, but also in increasing platelet counts."

The Phase 2 clinical trial will be conducted in 2 parts. In Part 1, approximately six participants will be enrolled in each of up to four cohorts of ascending doses of KER-050 to be administered by subcutaneous injection every four weeks for up to four cycles. In Part 2, the dose selected from Part 1 will be evaluated in up to 30 participants. The primary objective of the trial is to confirm the safety and tolerability of KER-050 in MDS participants with ring sideroblasts (RS+) as well as in participants without ring sideroblasts (non-RS).

About Myelodysplastic Syndromes (MDS)

Myelodysplastic syndromes ("MDS") is a collection of bone marrow disorders characterized by ineffective hematopoiesis, often with a dramatic expansion of progenitor cells that are unable to mature into functioning blood cells. In the United States, there are 60,000 to 170,000 patients with MDS and 15,000 to 20,000 new cases of MDS reported each year. MDS predominantly affects older adults, with approximately 75% of patients aged 60 years or older at diagnosis. Median survival ranges from approximately nine years for very low-risk patients to less than a year for high-risk patients.

Cytopenias in MDS are caused by defects occurring across the various stages of hematopoiesis, from the self-renewal of progenitor cells to differentiation in early through terminal stages. Anemia is the most frequent consequence of ineffective hematopoiesis in patients with MDS due to low red blood cell production, and impacts 90% of MDS patients, with approximately 40% becoming transfusion dependent. Another consequence is thrombocytopenia, a deficiency of platelets in the blood, which can lead to impaired blood clotting and higher risk of bleeding. The prevalence of thrombocytopenia in patients with MDS has been reported at 40% to 65%. A deficiency of neutrophils in the blood, or neutropenia, also increases the risk of serious infections in patients with MDS and has been reported to affect approximately 20% of patients with MDS.

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 MDS and in patients with myelofibrosis. Keros recently completed a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of KER-050 in healthy post-menopausal women, and has commenced a Phase 2 clinical trial in patients with MDS evaluating KER-050 for the treatment of cytopenias, including anemia and thrombocytopenia. Keros also plans to commence a Phase 2 clinical trial evaluating KER-050 for the treatment of patients with myelofibrosis-associated cytopenias in 2021.

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 elevated levels of hepcidin, the key regulator of iron absorption and recycling, 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Many factors could cause the actual results, performance or achievements that may be expressed or implied by such forward-looking statements to vary from those described herein should one or more of these risks or uncertainties materialize, including those risk factors discussed or referred to 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 August 13, 2020, 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.

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