Keros Therapeutics Announces Preliminary Topline Results from its Ongoing Phase 1 Clinical Trial Evaluating KER-012 in Healthy Volunteers

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LEXINGTON, Mass., May 18, 2022 (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 topline results from Part 1 of its Phase 1 clinical trial evaluating single and multiple ascending doses of KER-012 in healthy postmenopausal volunteers.

The ongoing trial is designed as a randomized, double-blind, placebo-controlled, two-part trial to assess the safety, tolerability and pharmacokinetics of KER-012. In Part 1 of this ongoing trial, 32 subjects received either a single 0.75, 1.5, 3 or 5 mg/kg dose of KER-012 and eight subjects received a single dose of placebo, each administered subcutaneously with an eight-week safety follow-up. The subjects were enrolled in sequential single-ascending dose escalation cohorts of ten subjects each.

KER-012 was generally well tolerated in Part 1 of this trial at dose levels up to 5 mg/kg, the highest dose level tested, when administered as a single dose. While one subject withdrew consent after receiving a single 1.5 mg/kg dose of KER-012 and did not complete the safety follow-up, there were no discontinuations due to treatment-related adverse events in Part 1 of this trial. No serious adverse events were reported in Part 1 of this trial. Additionally, the majority of the adverse events that were observed in Part 1 of this trial were mild in severity.

Preliminary topline results from Part 1 of this trial include the following:

- Pharmacokinetic parameters were observed to be generally dose proportional with increasing doses.
- Maximal target engagement was observed following a single 5 mg/kg dose of KER-012, with a mean (standard deviation, “SD”) 39.6 (12.7)% reduction in follicle-stimulating hormone levels observed on Day 22.
- Robust increases in markers of bone formation were observed:
    - Bone specific alkaline phosphatase increased, starting at the lowest dose of 0.75 mg/kg, with mean (SD) maximum increases from baseline of 36.4 (4.0)% at the highest dose of 5 mg/kg.
- No clinically meaningful changes in red blood cells or hemoglobin were observed in Part 1 of this trial.

“We are pleased to report the preliminary topline findings from Part 1 of the Phase 1 clinical trial in KER-012, as we observed target engagement and changes in bone remodeling markers consistent with the restoration of signaling of the bone morphogenetic protein (“BMP”) pathway, with no clinically meaningful observed changes in red blood cells or hemoglobin,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. “We believe these results support the potential of KER-012 as a treatment for diseases that are associated with reduced BMP signaling, such as pulmonary arterial hypertension (“PAH”), without a potentially dose-limiting red blood cell effect.”

Part 2 of this trial is ongoing, with dosing for Cohort 3 of Part 2 initiated at 4.5 mg/kg of KER-012, to be administered once every four weeks for three doses. Keros expects to report data from Part 2 of this trial in the second half of 2022.

Following the completion of this Phase 1 clinical trial, Keros expects to initiate a Phase 2 clinical trial of KER-012 in patients with PAH, and expects to share the trial design for the Phase 2 clinical trial in early 2023.

Conference Call and Webcast

Keros will host a conference call and webcast today, May 18, 2022 at 8:00 a.m. Eastern time to discuss the topline results from Part 1 of the KER-012 Phase 1 clinical trial. The conference call will be webcast live at https://event.webcasts.com/starthere.jsp?ei=1548072&tp_key=90cb438f4c. The live teleconference may be accessed by dialing (877) 405-1224 (domestic) or (201) 389-0848 (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 KER-012

KER-012 is designed to bind to and inhibit the signaling of TGF-ß ligands that suppress bone growth, including activin A and activin B. Keros believes that KER-012 has the potential to increase the signaling of BMP pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors. KER-012 is being developed for the treatment of PAH and for the treatment of disorders associated with bone loss, such as osteogenesis imperfecta and osteoporosis.

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. Keros' third product candidate, KER-012, is being developed for the treatment of PAH and for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta.

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-012; and the potential of KER-012 to treat diseases such as PAH without a dose-limiting red blood cell effect. 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 5, 2022, 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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