Keros Therapeutics, Inc. Announces Completion of Dosing of Planned Cohorts in KER-047 Phase 1 Trial and Provides Program Update

August 4, 2020 12:01 PM EDT

LEXINGTON, Mass., Aug. 04, 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 the completion of the planned cohorts in a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of its lead small molecule product candidate, KER-047, in healthy volunteers.

“We are pleased to report the topline findings from the completed cohorts in our Phase 1 clinical trial demonstrating target engagement and further delineating the relationship of activin receptor-like kinase-2 (“ALK2”) inhibition and hepcidin suppression. We believe the translation of biology from rodents to humans provides a strong rationale to evaluate KER-047 in anemias due to elevated levels of hepcidin and in fibrodysplasia ossificans progressiva (“FOP”), a rare musculoskeletal disorder resulting from aberrant ALK2 signaling,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros.

Keros has performed a preliminary analysis of single ascending and multiple ascending dose cohorts completed to date and plans to present the results from this Phase 1 clinical trial at a major medical conference later in 2020.

- The objectives of the Phase 1 clinical trial were to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic effects of single and multiple ascending dose levels of KER-047 in healthy volunteers. In the multiple ascending dose cohorts, KER-047 was administered as daily doses ranging from 50-350 mg for up to 7 days. The tolerability profile in healthy volunteers has been characterized in this Phase 1 clinical trial.
- There were no serious adverse events reported in either part of the trial. The most common adverse events observed in healthy volunteers in this trial were headache, nausea, vomiting, diarrhea, gastroenteritis, chills, pyrexia, myalgia, decreased appetite, lymphopenia, neutropenia, and liver enzyme increases. Dose-related decreases in lymphocytes were observed following peak increases in serum iron at the highest doses, which we believe is consistent with KER-047’s mechanism of action and suggestive of excessive mobilization and subsequent depletion of iron.
- Multiple pharmacodynamic biomarkers were included to assess KER-047's inhibition of ALK2. A reduction in hepcidin was observed following 7 days of dosing in the multiple ascending dose cohorts. Additionally, the reduction in hepcidin, increases in serum iron and increases in reticulocyte hemoglobin observed in healthy volunteers administered KER-047 is supportive of iron mobilization from tissue stores.

Based upon its preliminary analysis, Keros expects to expand its Phase 1 clinical trial to evaluate an additional two cohorts of healthy volunteers, which will help to further define dosing regimens to inform the design of upcoming Phase 2 clinical trials. Keros continues to expect commencement of a Phase 2 clinical trial in patients with iron-refractory iron deficiency anemia and other anemias with elevated hepcidin, including myelofibrosis, and a Phase 2 clinical trial in patients with FOP, both in the first half of 2021.

“Based on the tolerability and pharmacodynamic effects observed after 7 days of dosing in healthy volunteers, we believe there is a potential to develop several different dosing regimens for KER-047 for use in different indications, which we plan to further refine by evaluating two additional cohorts of healthy volunteers. We believe this will facilitate a more rapid exploration of safety and efficacy of relevant dosing regimen in the patient population,” added Dr. Seehra.

KER-047 has been developed by Keros under an exclusive patent license agreement with The General Hospital Corporation through Mass General Brigham Inc. and in collaboration with scientists at Massachusetts General Hospital, Brigham and Women’s Hospital and the National Center for Advancing Translational Sciences (“NCATS”) at the National Institutes of Health.

“At NCATS, we aim to reduce costly and time-consuming bottlenecks in the translational research pipeline in order to potentially speed the delivery of new products to patients,” said Christopher P. Austin, M.D., Director of NCATS. “A goal of the NCATS collaboration with Keros is to accelerate the development of a potential novel treatment for conditions with high unmet clinical needs.”

About KER-047

Keros’ lead small molecule product candidate, KER-047, is designed to selectively and potently inhibit activin receptor-like kinase-2, a Transforming Growth Factor-Beta receptor. 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, a rare musculoskeletal disorder.

About Mass General Brigham Inc.

Mass General Brigham Inc. is an integrated health care system, founded by Brigham and Women's Hospital and Massachusetts General Hospital, that offers patients a continuum of coordinated and high-quality care. In addition to its two academic medical centers, the system includes community and specialty hospitals, a health insurance plan, a physician network, community health centers, home health and long-term care services, and other health care entities. Mass General Brigham Inc. is a non-profit organization that is committed to patient care, research, teaching, and service to the community. In addition, Mass General Brigham Inc. is one of the nation's leading biomedical research organizations and is a principal teaching affiliate of Harvard Medical School.

About Massachusetts General Hospital

Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The MGH Research Institute conducts the largest hospital-based research program in the nation, with an annual research budget of more than $1 billion and comprises more than 8,500 researchers working across more than 30 institutes, centers and departments.

About Brigham Health

Brigham Health, a global leader in creating a healthier world, consists of Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, the Brigham and Women's Physicians Organization and many related facilities and programs. With more than 1,000 inpatient beds, approximately 60,000 inpatient stays and 1.7 million outpatient encounters annually, Brigham Health's 1,200 physicians provide expert care in virtually every medical and surgical specialty to patients locally, regionally and around the world. An international leader in basic, clinical and translational research, Brigham Health has nearly 5,000 scientists, including physician-investigators, renowned biomedical researchers and faculty supported by over $700 million in funding. Boston-based Brigham and Women's Hospital is a teaching affiliate of Harvard Medical School and dedicated to educating and training the next generation of health care professionals.

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 timing of its clinical trials for KER-047; the potential of KER-047 to treat anemias with elevated hepcidin and fibrodysplasia ossificans progressiva; and Keros' plans to present clinical data at an upcoming conference. 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 May 22, 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.

Investor Contact:

Julia Balanova
jbalanova@soleburytrout.com
646-378-2936