Keros Therapeutics Announces TROPOS Topline Data and Corporate Restructuring

May 29, 2025 10:55 AM EDT

Discontinues Development of Cibotercept in PAH

Announces Corporate Restructuring to Align Operations with Ongoing Strategic Priorities

LEXINGTON, Mass., May 29, 2025 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. ("Keros", the "Company" or "we") (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the transforming growth factor-beta ("TGF-ß") family of proteins, today announced topline data from the TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension ("PAH"), and provided a corporate update.

TROPOS Trial Results

TROPOS is a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial to evaluate cibotercept in combination with background therapy in patients with PAH. On December 12, 2024, the Company announced that it had voluntarily halted the 3.0 mg/kg and 4.5 mg/kg treatment arms based on the observation of pericardial effusions at those dose levels. Furthermore, on January 15, 2025, the Company announced that it had voluntarily halted all dosing in the trial, including the 1.5 mg/kg and placebo treatment arms, based on the ongoing safety review due to new observations of pericardial effusion adverse events. Following the early termination of the trial, patients continued to be monitored through their end-of-trial visits.

Following the analysis of all available safety and efficacy data from the TROPOS trial, the Company has decided to discontinue all development of cibotercept in PAH.

"Additional treatment options for individuals with PAH are critically needed," said Jasbir S. Seehra, Ph.D, Chair and Chief Executive Officer. "We are immensely grateful to the patients, investigators and Keros colleagues for their dedication to seeking new treatment options for this devastating disease."

The Company shared top-line results in a presentation that will be accessible in the Investors section of the Keros website at https://ir.kerostx.com. The Company plans to submit more detailed findings from the TROPOS trial at a future medical meeting.

The Company plans to further evaluate the appropriate development strategy for cibotercept, if any, in other indications following the completion of the strategic alternative review process.

Corporate Restructuring

In connection with the decision to discontinue all development of cibotercept in PAH and an assessment of its ongoing development programs, the Keros Board of Directors (the "Board") and management team have decided to reduce the Company's headcount by approximately 45%, after which the Company will have 85 full-time employees. The reduction in headcount will commence after the 60-day notice period required by the Worker Adjustment and Retraining Notification Act has elapsed, and as a result of these actions, Keros expects to realize average annualized cost savings of approximately $17 million.

Dr. Seehra added, "Consistent with our commitment to being data driven and taking action to best position Keros to drive sustainable stockholder value, we have identified opportunities to restructure our operations and reduce costs as we focus on our key ongoing development programs. As a result, we have made the difficult decision to reduce our workforce to better align with our strategic priorities. We appreciate the hard work and dedication of our impacted team members and we are committed to supporting them through this transition. Looking ahead, Keros maintains a robust balance sheet and we are making meaningful progress on our other development programs. Our focus remains on the execution of our strategy as we concurrently work to complete the ongoing review of strategic alternatives to maximize value for all stockholders."

As previously announced on April 10, 2025, with the assistance of outside financial and legal advisors, the Strategic Committee of the Board, which consists of independent and disinterested directors, is continuing to evaluate a comprehensive range of strategic alternatives, including but not limited to a sale of the Company or other business combination transaction, continued investment in the Company's pipeline, and/or return of excess capital to stockholders. Keros intends to provide a preliminary update regarding the status of the process no later than June 9, 2025.

About TROPOS (NCT05975905)
TROPOS is a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial to evaluate cibotercept in combination with background therapy in patients with PAH. The primary objective of this trial is to evaluate the effect of cibotercept on pulmonary hemodynamics compared to placebo in participants on background PAH therapy. The key secondary objective of this trial is to evaluate the effect of cibotercept on exercise capacity compared to placebo on participants on background PAH therapy.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the TGF-ß family of proteins. Keros is a leader in understanding the role of the TGF-ß family of proteins, which are master regulators of the growth, repair and maintenance of a number of tissues, including blood, bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, Keros has discovered and is developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros' lead product candidate, KER-065, is being developed for the treatment of neuromuscular diseases, with an initial focus on Duchenne muscular dystrophy. Keros' most advanced product candidate, elritercept (KER-050), is being developed for the treatment of cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndrome and in patients with myelofibrosis.

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,” “continue,” “expects,” “enable,” “potential” and “will” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning the intended benefits and outcome of the strategic review process (including timing of announcing an update), expected development and regulatory pathway and therapeutic benefits of cibotercept and the Company’s other product candidates, any anticipated benefits of the reduction in force (including anticipated cost savings), and the Company’s cash runway. 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: whether the objectives of the strategic alternative review process will be achieved; the terms, structure, benefits and costs of any strategic transaction; the timing of any transaction and whether any transaction will be consummated at all; the risk that the strategic alternatives review, workforce reduction and the announcements thereof could have an adverse effect on the ability of the Company to retain and hire key personnel and maintain relationships with partners, suppliers, employees, stockholders and other business relationships and on its operating results and business generally; the risk the strategic alternatives review could divert the attention and time of the Company’s management; the risk of any unexpected costs or expenses resulting from the review; the risk of any litigation relating to the review; 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 product candidates, KER-065 and elritercept; that Keros may be delayed in initiating, enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; the risk that circumstances surrounding or leading up to our 2025 Annual Meeting may change; Keros’ ability to obtain, maintain and protect its intellectual property; Keros’ dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; the impact of the workforce reduction, including any unexpected costs, expenses, or litigation.

These and other risks are described more fully in Keros’ filings with the Securities and Exchange Commission (the “SEC”), including the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q, filed with the SEC on May 6, 2025, 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.

Contacts

Investor Contact:
Justin Frantz
jfrantz@kerostx.com
617-221-6042

Media Contact:
Mahmoud Siddig / Adam Pollack / Viveca Tress
Joele Frank, Wilkinson Brimmer Katcher
(212) 355-4449