Keros Therapeutics Announces Update on the Phase 2 TROPOS Trial

December 12, 2024 11:00 AM EST

- *Keros will host an update call and webcast today, December 12, 2024, at 8:00 a.m. ET*

LEXINGTON, Mass., Dec. 12, 2024 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros” or the “Company”) (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 that it has voluntarily halted dosing in the 3.0 mg/kg and 4.5 mg/kg treatment arms in the ongoing TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension (“PAH”), based on a safety review due to the unanticipated observation of pericardial effusion adverse events in the trial.

“We are working diligently to gain a better understanding of these unanticipated findings,” said Jasbir S. Seehra, Ph.D., Chair and CEO. “Above all, patient safety is our top priority when conducting any clinical trial. We will work with the investigators, the U.S. Food and Drug Administration (“FDA”) and other relevant regulatory authorities to address this as quickly as possible.”

The TROPOS trial is fully enrolled, and dosing in the 1.5 mg/kg treatment arm remains ongoing following completion of a risk and benefit assessment of the data from the ongoing trial that was conducted by the independent Data Monitoring Committee (“DMC”) followed by a select group of unblinded individuals at Keros. The decision to halt the dosing in 3.0 mg/kg and 4.5 mg/kg treatment arms and continue dosing in the 1.5 mg/kg treatment arm was made in consultation with the independent DMC for the trial. The Company intends to continue ongoing safety and efficacy data collection for all treatment arms in the trial. The Company has notified investigators and certain regulatory authorities, including the FDA, about this decision, and is in the process of notifying other relevant regulatory authorities. The Company continues to expect to present topline data from all treatment arms in this trial in the second quarter of 2025. The Company is working diligently to investigate and address this matter and expects to provide additional information when there is a material update.

Conference Call and Webcast Information

Keros will host a conference call and webcast today, December 12, 2024, at 8:00 a.m. Eastern time. The conference call will be webcast live at: https://event.choruscall.com/mediaframe/webcast.html?webcastid=6k3fkWkW. The live teleconference may be accessed by dialing (877) 407-0309 (domestic) or (201) 389-0853 (international). An archived version of the call will be available in the investors section of the Keros website at http://ir.kerostx.com/ for 90 days following the conclusion of the call.

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 Cibotercept

Cibotercept is designed to bind to and inhibit the signaling of TGF-β ligands that stimulate smooth muscle hypertrophy and fibrosis, including activin A, activin B and myostatin. Keros believes that cibotercept has the potential to increase the signaling of bone morphogenic protein (“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. Cibotercept is being developed for the treatment of PAH and for the treatment of cardiovascular disorders.

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 “expect” and “will” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros’ expectations regarding its progress and the design, objectives and timing of its clinical trial for cibotercept, including expected timing for data readout for the TROPOS trial; the response of FDA or any regulatory authorities to our voluntary actions with respect to the TROPOS trial; and the potential of cibotercept to increase the signaling of BMP pathways to treat diseases such as PAH. 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 product candidates, cibotercept, elritercept and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical trials; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; competition from third parties that are developing products for similar uses; Keros’ ability to obtain, maintain and protect its intellectual property; and Keros’ dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

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 November 6, 2024, 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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