Keros Therapeutics Announces Update on Enrollment in the Phase 2 TROPOS Trial

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LEXINGTON, Mass., Sept. 03, 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 the Company has closed screening for the TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension (“PAH”). As a result, Keros expects to complete enrollment by the end of September and present topline data in the second quarter of 2025.

“We are very pleased to announce the closing of screening in the TROPOS trial,” said Jasbir S. Seehra, Ph.D., Chair and Chief Executive Officer. “The tremendous demand and speed we have observed in enrolling this trial will enable us to present topline data earlier than anticipated, now expected in the second quarter of 2025.”

“We want to thank the TROPOS investigators, research staff and their patients for their participation in this important clinical research,” said Chris Rovaldi, President and Chief Operating Officer. “This milestone, which could not have been achieved without their commitment, brings us one step closer to bringing a potentially differentiated treatment option to patients living with PAH.”

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.

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. The Company 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, elritercept (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’ second product candidate, cibotercept, is being developed for the treatment of PAH and for the treatment of cardiovascular disorders. Keros’ third product candidate, KER-065, is being developed for the treatment of obesity and for the treatment of neuromuscular diseases.

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 “expects,” “enable,” “potential,” “will” 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 cibotercept (including expected timing for enrollment completion and data readout for the TROPOS trial). 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, elritercept, cibotercept and KER-065; 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; 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 August 7, 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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