Keros Therapeutics Announces U.S. FDA Fast Track Designation for KER-050 in Lower-Risk Myelodysplastic Syndromes

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LEXINGTON, Mass., March 14, 2024 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros”) (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 U.S. Food and Drug Administration (“FDA”) has granted Fast Track designation for KER-050 (elritercept) for the treatment of anemia in adult patients with very low-, low-, or intermediate-risk myelodysplastic syndromes (“MDS”).

“Receiving Fast Track designation for KER-050 underscores the need for novel treatment options to address the serious unmet medical needs of people living with lower-risk MDS,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “We look forward to working closely with the FDA as we engage on the design of a Phase 3 clinical trial evaluating KER-050 in lower-risk MDS in the first half of this year.”

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of investigational treatments that demonstrate a potential to address unmet medical needs in serious or life-threatening conditions. Programs with Fast Track designation can benefit from early and more frequent interactions with the FDA to discuss the product candidate’s development plan in addition to a rolling submission of the marketing application. Product candidates with Fast Track designation may also be eligible for priority review and accelerated approval.

About KER-050

Keros’ lead product candidate, KER-050, is an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-ß receptor known as activin receptor type IIA that is fused to the portion of the human antibody known as the Fc domain. KER-050 is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with myelofibrosis.

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. We are 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, we have discovered and are developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros’ lead product candidate, KER-050 (elritercept), is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with myelofibrosis. Keros’ second product candidate, KER-012, is being developed for the treatment of pulmonary arterial hypertension 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 “look forward,” “plan” and “potential” 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-050, including its regulatory plans. 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, KER-050, KER-012 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 Annual Report on Form 10-K, filed with the SEC on February 28, 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.

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