Keros Therapeutics Announces the First Patient Dosing in the Phase 3 RENEW Clinical Trial of Elritercept

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Milestone payment of $10 million triggered under the global license agreement with Takeda

LEXINGTON, Mass., July 17, 2025 (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 first patient was dosed in the Phase 3 RENEW clinical trial of elritercept in adults with transfusion-dependent anemia with very low, low, or intermediate risk myelodysplastic syndromes (“MDS”). The dosing of the first patient triggers a $10 million milestone payment to Keros under the global license agreement with Takeda.

“The initiation of patient dosing in the RENEW trial marks an important next step in evaluating elritercept as a potentially differentiated therapy for patients with MDS,” said Jasbir S. Seehra, Ph.D., Chair and Chief Executive Officer of Keros. “We are pleased to have achieved this milestone alongside our partner Takeda and look forward to seeing elritercept’s potential further explored for patients in need.”

Under the terms of the global license agreement with Takeda to further develop, manufacture and commercialize elritercept worldwide outside of mainland China, Hong Kong and Macau, which became effective on January 16, 2025, Keros received a $200 million upfront cash payment in February 2025, and is eligible to receive development, commercial and sales milestones with the potential to exceed $1.1 billion. Keros will also be eligible to receive tiered royalties on net sales.

About the Elritercept Phase 3 RENEW Clinical Trial

The elritercept Phase 3 RENEW clinical trial (NCT06499285) is a global, randomized, double-blind, placebo-controlled trial in adults with transfusion-dependent anemia with very low, low, and intermediate risk MDS. The primary objective is to evaluate the efficacy of elritercept in reducing red blood cell transfusions.

About Elritercept (KER-050)

Elritercept 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. 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 MF.

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,” “intention,” “potential” and “will” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: elritercept as a potentially differentiated therapy for patients with MDS; and the expected milestone payment under the license agreement. 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-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; 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 (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.

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