Keros Therapeutics to Develop KER-065 for the Treatment of Obesity

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- *Keros commenced a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-065 in healthy volunteers*
- *Keros expects to report initial data from this Phase 1 clinical trial in the first quarter of 2025*
- *Preclinical data showed potential proof-of-mechanism of KER-065 for the treatment of obesity*
- *Keros believes these preclinical data support developing KER-065 for the treatment of obesity, and Keros plans to initiate a proof-of-concept trial of KER-065 in obese patients following completion of this Phase 1 clinical trial*

LEXINGTON, Mass., Jan. 03, 2024 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros” 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 that it plans to develop KER-065, a novel ligand trap designed to bind to and inhibit TGF-ß ligands, including myostatin (GDF8) and activin A, for the treatment of obesity.

“Obesity is a complex and chronic disease associated with numerous comorbidities and a growing prevalence in patients. We believe there is a need for additional treatment options, including one that leads to weight loss without an associated loss of muscle and a potential for frailty. Based on our preclinical data, we believe that KER-065 has the potential to treat obesity without those limitations, by increasing skeletal muscle, reducing fat mass through an increase in energy expenditure, improving insulin sensitivity and improving cardiac function,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. “To that end, we recently commenced our Phase 1 clinical trial evaluating KER-065 in healthy volunteers and, following its successful completion, plan to initiate a proof-of-concept trial of KER-065 in obese patients.”

Preclinical data showed potential proof-of-mechanism of KER-065 for the treatment of obesity with a research form of KER-065 (“RKER-065”) and a research form of another ActRII ligand trap closely related to KER-065 (“RKER-034”). Specifically, in preclinical studies:

- KER-065 and KER-034 each showed high affinity for and potent inhibition of ligands, including activin A and myostatin (GDF8), which are key negative regulators of muscle and bone growth.
- RKER-065 and RKER-034 had equivalent increases in skeletal muscle in the diet-induced obesity (“DIO”) mouse model.
- A combination treatment of RKER-034 and a glucagon-like peptide-1 receptor agonist (“GLP-1 RA”) increased lean mass in the DIO mouse model, as compared to the loss of lean mass observed in obese mice treated with the GLP-1 RA alone.
    - While monotherapy dosing of the GLP-1 RA and RKER-034 led to reductions in fat gain compared to untreated obese mice, the combination treatment resulted in fat loss compared to untreated obese mice.

Based on this preclinical data, Keros believes that KER-065 has the potential to treat obesity both as a monotherapy and in combination with GLP-1 RA by increasing muscle mass and decreasing fat mass.

About the Ongoing Phase 1 Clinical Trial of KER-065 in Healthy Volunteers

Keros is conducting a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-065 in healthy volunteers.

The primary objectives of this trial are to assess safety, tolerability and pharmacokinetics of KER-065. Exploratory endpoints include assessments of the pharmacodynamic effect on bone, adipose, muscle, cardiac tissue and fibrosis. To aid in the assessment of adipose tissue, volunteers in Part 2 of this trial will be required to have a BMI between ≥ 27 and ≤ 33 kg/m^2 to be enrolled.

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 blood cells and a number of tissues, including bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, we have discovered and are developing large and small molecules that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros’ lead protein therapeutic 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 myelodysplastic syndromes 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 "believes," "expects," "plans," "potential," "would" and "future" or similar expressions such as "look forward" 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-065; and the potential of KER-065 to treat obesity without an associated loss of muscle and potential for frailty, both as a monotherapy and in combination with GLP-1 RAs. 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 Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2023, 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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