Keros Therapeutics Presents Results from a Preclinical Study of RKER-012 at the American Heart Association 2021 Scientific Sessions

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LEXINGTON, Mass., Nov. 15, 2021 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need, today announced that it presented results from a preclinical study of a research form of KER-012 (“RKER-012”) at the American Heart Association (“AHA”) 2021 Scientific Sessions held November 13 through 15, 2021.

RKER-012 reduced cardiac dysfunction, cardiac remodeling and cardiac fibrosis in a pulmonary arterial banding mouse model of right ventricle overload.

- *KER-012, a Novel Modified ActRII Ligand Trap, Attenuated Cardiac Pathology in a Pulmonary Arterial Banding Model of Right Ventricle Overload*

Keros used a pulmonary arterial banding (“PAB”) model of right ventricle overload to evaluate the cardio-protective activity of RKER-012 in mice. Mice either underwent sham or PAB surgery. Following these procedures, sham mice received vehicle and PAB mice received either vehicle (“PAB-vehicle”) or 10 mg/kg of RKER-012 (“PAB-RKER-012”) twice weekly for three weeks. Relative to sham mice, PAB-vehicle and PAB-RKER-012 mice had elevated pulmonary arterial pressures on Day 1 that persisted until Day 21, indicating that the PAB surgery worked as intended.

PAB-vehicle mice exhibited diminished cardiac function and had markers of cardiac remodeling. Conversely, treatment with RKER-012 in the PAB mice prevented changes in cardiac function and tissue remodeling, which provides support that RKER-012 has a cardio-protective mechanism of action that could potentially provide benefit in diseases such as pulmonary arterial hypertension (“PAH”).

“In a separate preclinical study, we demonstrated that KER-012 did not increase hemoglobin or red blood cells in non-human primates, which we believe will translate to a lack of a red blood cell effect in humans, as well. These data, along with the preclinical data we presented at the AHA 2021 Scientific Sessions, support that the cardio-protective effects can be independent from red blood cell increases. Accordingly, we believe KER-012 has the potential to provide benefit in PAH without affecting red blood cells or hemoglobin,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros.

About KER-012

KER-012 is designed to bind to and inhibit the transforming growth factor-Beta ligands that suppress bone growth, including activin A and activin B, in order to promote bone growth to potentially treat diseases such as osteogenesis imperfecta and osteoporosis. Keros believes that KER-012 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. KER-012 is being developed for the treatment of disorders associated with bone loss, such as osteogenesis imperfecta and osteoporosis, and for the treatment of PAH. Keros is conducting a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-012 in healthy volunteers. Keros expects to report initial data from Part 1 of this trial in the first half of 2022 and additional data from Part 2 of this trial in the second half of 2022.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematologic and musculoskeletal disorders with high unmet medical need. Keros is a leader in understanding the role of the transforming growth factor-Beta family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. Keros’ lead protein therapeutic product candidate, 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’ lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva. Keros’ third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH.

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," "expects," "intends," “plans,” “potential,” "projects,” “would” and "future" 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 timing of its clinical trial for KER-012; and the potential of KER-012 to treat PAH without affecting red blood cells or hemoglobin. 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 lead product candidates, KER-050 and KER-047; 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; Keros’ dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; Keros’ ability to enter into new collaborations; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

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 4, 2021, 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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