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Pasithea Therapeutics Announces Positive In Vivo Preclinical Efficacy Data for PAS-004 from NRAS Mutation Cancer Xenograft Models

-- Preclinical data continues to demonstrate PAS-004's potentially superior properties as compared to FDA approved MEK inhibitors --

-- Once daily dose of PAS-004 delivers anti-tumor efficacy in*in vivo* NRAS mutation cancer models --

SOUTH SAN FRANCISCO, Calif. and MIAMI, Dec. 11, 2023 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a biotechnology company focused on the discovery, research, and development of innovative treatments for Central Nervous System (CNS) disorders, today announced positive preclinical results from two *in vivo* studies evaluating the anti-tumor efficacy of PAS-004 in NRAS mutation cancer xenograft models.

In the first study, PAS-004 exhibited dose-dependent anti-tumor efficacy in the lung cancer NCI-H1299 cell-line-derived xenograft model. PAS-004 at dose levels of 10 mg/kg and 5 mg/kg, once daily, significantly inhibited tumor growth as compared to vehicle control. The anti-tumor efficacy of PAS-004, when taken at equivalent doses was shown to be superior to that of binimetinib and selumetinib.

In the second study, PAS-004 exhibited dose-dependent anti-tumor efficacy in the liver cancer xHepG2 cell-line-derived xenograft model. PAS-004 at dose levels of 10 mg/kg and 5 mg/kg, once daily, produced signigicant antitumor activities as compared to vehicle control. The anti-tumor efficacy of PAS-004, when taken at equivalent doses was shown to be similar to that of binimetinib and superior to that of selumetinib.

These studies were conducted to provide further support of PAS-004 ahead of the Company's planned first-in-human Phase 1 open-label dose escalation trial in patients with MAPK pathway-driven advanced solid tumors harboring RAS, RAF or NF1 mutations or patients who have failed BRAF/MEK inhibition. The Phase I study is expected to start as early as the first quarter of 2024, following acceptance of the Company's Investigational New Drug Application (IND) with the FDA.

"PAS-004, with its macrocyclic chemical structure, has demonstrated optimal drug like properties and dose-dependent response *in vivo* across several preclinical cancer, LMNA cardiomyopathy and neurofibromatosis type 1 (NF1) models," commented Dr. Graeme Currie, Chief Development Officer of Pasithea. "Sustained suppression of extracellular signal-regulated kinases (pERK) is necessary to drive efficacy in both cancer and other RASopathies, such as NF1. Our current modeling suggests we will have a longer half-life in

humans than existing MEK inhibitors and when coupled with our preclinical profile, we believe a once-a-day or less frequent dosing regimen is likely to be achieved for PAS-004, which we hope will lead to improved compliance when compared to existing therapies, as well as better combinability with other cancer agents," concluded Dr. Currie.

About PAS-004

PAS-004 is a small molecule allosteric inhibitor of MEK 1/2, which are dual-specificity protein kinases, in the MAPK signaling pathway. The MAPK pathway has been implicated in a variety of diseases, as it functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that, when abnormally activated, are critical for the formation and progression of tumors, fibrosis and other diseases. MEK inhibitors block phosphorylation (activation) of extracellular signal-regulated kinases (ERK). Blocking the phosphorylation of ERK can lead to cell death and inhibition of tumor growth. Existing FDA approved MEK inhibitors are marketed for a range of diseases, including certain cancers and neurofibromatosis type 1 (NF1). We believe these MEK inhibitors suffer from certain limitations, including known toxicities. Unlike current FDA approved MEK inhibitors, PAS-004 is macrocyclic, which we believe may lead to improved pharmacokinetic and safety (tolerability) profiles. Cyclization offers rigidity for stronger binding with drug target receptors. PAS-004 was designed to provide a longer half-life with what we believe is a better therapeutic window. Further, we believe the potency and safety profile that PAS-004 has demonstrated in preclinical studies may also lead to stronger and more durable response rates and efficacy, as well as better dosing schedules. PAS-004 has been tested in a range of mouse models of various diseases and has completed preclinical testing and animal toxicology studies. Additionally, PAS-004 has received orphan-drug designation from the FDA for the treatment of NF1.

About Pasithea Therapeutics Corp.

Pasithea is a biotechnology company focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders and RASopathies. With an experienced team of experts in the fields of neuroscience, translational medicine, and drug development, Pasithea is developing new molecular entities for the treatment of neurological disorders, including Neurofibromatosis type 1 (NF1), Solid Tumors, and Amyotrophic Lateral Sclerosis (ALS).

Forward Looking Statements

This press release contains statements that constitute "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include all statements, other than statements of historical fact, regarding the Company's current views and assumptions with respect to future events regarding its business, as well as other statements with respect to the Company's plans, assumptions, expectations, beliefs and objectives, the success of the Company's current and future business strategies, product development, preclinical studies clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of the Company. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-

looking statements, which are based on information available to the Company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties, including factors set forth in the Company's most recent Form 10-K, Form 10-Q and other factors set forth in the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other filings made with the U.S. Securities and Exchange Commission (SEC). Thus, actual results could be materially different. The Company undertakes no obligation to update these statements whether as a result of new information, future events or otherwise, after the date of this release, except as required by law.

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