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Pasithea Therapeutics Announces Opening of Enrollment in the U.S. for its Phase 1 Trial of PAS-004

-- Activation of four U.S. sites for Phase 1 clinical trial of PAS-004 to evaluate safety, dose, key biomarker data and preliminary efficacy --

-- Plans to open three additional sites in Eastern Europe in the coming months --

-- Preliminary interim data expected in 2H 2024 --

SOUTH SAN FRANCISCO, Calif. and MIAMI, Feb. 13, 2024 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a clinical-stage biotechnology company developing PAS-004, a next-generation macrocyclic MEK inhibitor, for the treatment of neurofibromatosis type 1 (NF1) and other cancer indications, today announced the activation of four clinical trial sites in the United States. These U.S. clinical trial sites in Texas and Virginia are now open and actively enrolling patients.

This announcement follows the approval from the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for PAS-004, and FDA review of the protocol for the Company's Phase 1 multicenter, open-label trial of PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition.

The objective of the Phase 1 study is to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of PAS-004 as well as to evaluate the preliminary anticancer activity (efficacy) of PAS-004 and to define the preliminary recommended Phase 2 dose.

The Company's clinical development plan for PAS-004 following the Phase 1 study is to begin a Phase 2 clinical trial in NF1 pediatric and adult patients as soon as safety and PK are established.

Pasithea has selected Novotech as the clinical research organization (CRO) for the Phase 1 trial and will be collaborating in the U.S. with NEXT Oncology, led by Dr. Anthony Tolcher M.D., along with Dr. Ildefonso Rodriguez M.D., acting as principal investigator for the San Antonio, TX site. There are also three other clinical trial sites in Eastern Europe that are expected to open in the coming months.

"Activating our four clinical trial sites in the U.S. is a significant milestone in Pasithea's mission towards developing PAS-004 as a potential best-in-class next-generation MEK inhibitor. We recognize the significant unmet needs and limited treatment options for patients with MAPK pathway-driven advanced solid tumors as well as NF1. We are ready to screen and enroll subjects in the coming month and look forward to gaining insight into the safety,

tolerability and initial efficacy of PAS-004." said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea.

PAS-004 is the first macrocyclic MEK inhibitor to enter human clinical trials, with an expected extended half-life in humans which may provide better compliance rates as well as improved efficacy in NF1. Macrocycles are known to exhibit stronger binding, better solubility and longer half-life with more selectivity and less off target effect as compared to acyclic small molecules.

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), which 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, which may provide seven years of marketing exclusivity upon approval of an NDA.

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 other diseases. 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 and 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 Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other filings made with the U.S. Securities and Exchange Commission. Thus, actual results could be materially different. The Company undertakes no obligation to update these forward-looking 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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