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Pasithea Therapeutics Announces FDA Acceptance of IND Application to Evaluate PAS-004 in Advanced Cancer Patients

-- PAS-004 is the first macrocyclic MEK inhibitor to enter human clinical trials --

-- Phase 1 dose escalation study in patients with MAPK pathway driven advanced solid tumors to begin in Q1 2024 –

-- Initial readout expected as early as Q3 2024 –

SOUTH SAN FRANCISCO, Calif. and MIAMI, Jan. 02, 2024 (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 the Investigational New Drug Application (IND) clearance to proceed by the U.S. Federal Drug Administration (FDA) to evaluate PAS-004, a macrocyclic MEK (1/2) inhibitor, in patients with MAPK pathway driven advanced solid tumors with a documented RAS, RAF or NF1 mutation or patients who have failed BRAF/MEK inhibition. Pasithea expects to dose the first patient in the first quarter of 2024.

The objectives of the dose escalation study are to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics as well as anti-tumor responses of PAS-004 as monotherapy in up to 36 advanced cancer patients with preliminary early data expected as early as Q3 2024.

"Receiving a study may proceed notification from the US FDA is a significant milestone in Pasithea's maturation into a clinical stage company developing PAS-004 as a potential best-in-class next generation MEK inhibitor and demonstrates our ability to execute on our objectives," said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "We believe PAS-004 has the potential to improve clinical responses in cancer patients as a monotherapy as well as provide a more tolerable and better dosing profile. After we have established a preliminary recommended phase 2 dose, we will use this information to bridge to dosing for Neurofibromatosis type 1 patients. We look forward to working with our clinical partners to start this study in the United States and Eastern Europe shortly."

Administered orally, PAS-004 is expected to be an once day or less frequent dose which may provide better compliance rates as well as superior efficacy. PAS-004 is the first macrocyclic MEK inhibitor to enter human clinical trials. Macrocycles exhibit unique drug-like profiles because of their cyclic structure, potentially improving bioavailability, binding affinity, and overall pharmacokinetics in comparison to acyclic counterparts.

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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