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Pasithea Therapeutics Announces Outcome of Pre-IND Meeting with FDA for PAS-004 Clinical Development

-- Company on track to submit PAS-004 IND application in current quarter --

-- Pasithea plans to begin PAS-004 Phase 1 dose escalation trial in advanced solid tumor patients harboring RAS, RAF and NF1 mutations --

SOUTH SAN FRANCISCO, Calif. and MIAMI, Nov. 29, 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, announced receipt of written responses to questions submitted for a Type 2 pre-Investigational New Drug Application (IND) meeting with the U.S. Food and Drug Administration (FDA) regarding clinical development plan for PAS-004. The FDA's positive feedback and guidance include a recommendation to begin dosing in patients who will benefit from treatment rather than in healthy volunteers. PAS-004 was granted orphan drug designation for the treatment of NF1 in November 2020.

"We are pleased with our PAS-004 Pre-IND meeting minutes which guide us to dose patients who will benefit from treatment. We are excited to begin testing PAS-004 in a first-in-human Phase 1 dose escalation trial in advanced solid tumor patients harboring RAS, RAF and NF1 mutations including KRAS, NRAS, BRAF and NF1 mutations, who have not responded or recurred following treatment with available therapies as early as the first quarter of 2024 following acceptance of the IND by the FDA", stated Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea.

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 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 to support an IND application with the FDA that we plan to submit in the fourth quarter of 2023. 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 primarily 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, 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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