February 5, 2025

Pasithea Therapeutics Announces Positive Safety Review Committee (SRC) Recommendation from its ongoing Phase 1 Clinical Trial of PAS-004 in Advanced Cancer

- SRC recommended that the trial escalate to the next dose level of 22mg capsule
- No dose-limiting toxicities (DLT's) or rash observed to date in either capsule or tablet formulations

MIAMI, Feb. 05, 2025 (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 that the external Safety Review Committee recommended that the Company's Phase 1 clinical trial of PAS-004 in advanced cancer should proceed to cohort 5, 22mg capsule, without modification. This recommendation was based on the review of the safety data from three patients in cohort 4A (15mg capsule) and the absence of any dose limiting toxicities (DLT's). In addition, no rash has been observed to date in any of the first 14 patients who have been dosed with PAS-004 in either capsule (12 patients) or tablet (2 patients) formulation. Rash is a common adverse event (AE) that is observed at low doses with competitor MEK inhibitors and may lead to the high discontinuation rate in real world practice.

"As we are observing substantial exposure levels of PAS-004, we remain encouraged by the safety profile PAS-004 continues to exhibit," stated Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "With the differentiated profile of PAS-004, we believe it is possible that this highly specific macrocyclic MEK inhibitor with a half life of greater than 60 hours may change the treatment paradigm for patients with NF1 and inoperable plexiform neurofibromas. We are looking forward to presenting updated pharmakokinetic (PK) and pharmacodynamic (PD) data during Q1 2025."

The ongoing Phase 1 clinical trial is a multi-center, open-label, dose escalation 3+3 study design to evaluate the safety, tolerability, pharmacokinetic (PK), pharmacodynamic (PD), and preliminary efficacy 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 (NCT06299839).

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 statements regarding the Company’s ongoing Phase 1 clinical trial and the safety, tolerability, pharmacokinetic (PK), pharmacodynamics (PD) and preliminary efficacy of PAS-004, as well as all other 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 risks that future clinical trial results may not match results observed to date, may be negative or ambiguous, or may not reach the level of statistical significance required for regulatory approval, as well as 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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