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Pasithea Therapeutics Announces Opening of European Clinical Trial Sites and Completes Initial Dosing of Cohort 4

-- Interim data from Cohort 4 expected Q1 2025 --

MIAMI, Jan. 14, 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 it has opened three clinical trial sites in Eastern Europe. These sites in Romania and Bulgaria are actively recruiting patients along with the four open sites in the United States, for Pasithea's PAS-004 Phase 1 trial.

In Eastern Europe, Pasithea is working with Arensia Exploratory Medicine, Institute of Oncology Bucharest, Arensia Exploratory Medicine, Institute of Oncology Cluj-Napoca, and Arensia Exploratory Medicine, Multiprofile Hospital for Active Treatment Sveta Sofia- EOOD.

In addition, Pasithea has completed initial dosing of three patients in Cohort 4A (15mg capsule). Patient recruitment for Cohort 4B is ongoing (4mg tablet). The Company plans to present interim safety and pharmacokinetic (PK) data from Cohorts 4A and 4B in Q1 2025.

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea stated, "We are pleased to be working with Arensia in Eastern Europe, allowing PAS-004 to be tested in patients with tumor types more sensitive to single agent MEK treatment or patients who have previously failed first-generation MEK inhibitors."

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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