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Pasithea Therapeutics Announces Completion of Enrollment and Initial Dosing of Patients in Cohort 6 from its Phase 1 Trial of PAS-004 in Advanced Cancer Patients

MIAMI, April 29, 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 MAPK pathway driven cancer indications, today announced the Company has completed enrollment and initial dosing of three subjects in Cohort 6 with 30 mg capsules of PAS-004.

"We are pleased to have recruited, enrolled and commenced dosing of the initial three subjects in Cohort 6 more rapidly than anticipated and we currently expect to complete enrollment of all patients in the trial by the end of 2025," said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea.

The ongoing Phase 1 clinical trial is a multi-center, open-label, dose escalation 3+3 study design to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (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 clinical-stage biotechnology company focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders, RASopathies and MAPK pathway driven tumors.

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 of PAS-004 in advanced cancer patients, the Company's planned Phase 1/1b clinical trial of PAS-004 in adult NF1 patients, 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, pre-clinical 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.

Pasithea Therapeutics Contact

Patrick Gaynes
Corporate Communications
pgaynes@pasithea.com



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