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Pasithea Therapeutics Announces Completion of Enrollment and Initial Dosing of Cohort 2 following Positive Safety Review Committee (SRC) Recommendation for PAS-004 in Ongoing Phase 1 Clinical Trial

-- On track for initial interim safety and PK data release in Q3 2024 --

MIAMI, June 13, 2024 (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 indications, announced today that an independent Safety Review Committee (SRC) has completed its safety review of data from the first dose cohort (2mg) treated in the ongoing Phase 1 clinical trial (NCT06299839) 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.

Based on these findings, the SRC recommended that the trial escalate to the next dose level (4mg) without modifications. This recommendation was based on the absence of any dose limiting toxicities (DLT's) or clinically relevant treatment-emergent adverse events in the initial cohort of 3 patients. The Company has now completed enrollment and initial dosing of 3 patients in the second cohort.

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea stated, "We are pleased to have rapidly enrolled and completed first dosing of the participants in the second cohort following the SRC's positive recommendation to advance to 4mg of PAS-004. We look forward to continuing to develop PAS-004 as a potential treatment for solid tumors as well as cutaneous and plexiform neurofibromas in NF1 patients. We remain on track to present our initial safety and pharmacokinetic (PK) data in the third quarter of 2024."

The Phase 1 trial is a multicenter, open-label, dose escalation study evaluating the safety, tolerability, and pharmacokinetics (PK) and pharmacodynamics (PD) 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. The primary objective of the study is to assess the safety and tolerability of PAS-004, with secondary objectives including PK and PD parameters, an evaluation of the preliminary anticancer activity (efficacy) of PAS-004 and defining the preliminary recommended Phase 2 dose(s).

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 and clinical trials, clinical and regulatory timelines, market opportunity, competitive position, 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 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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