November 20, 2024

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 15mg capsule --

-- No dose-limiting toxicities (DLTs) observed to date --

-- No rash observed to date --

MIAMI, Nov. 20, 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 cancer indications, today announced that the external Safety Review Committee recommended proceeding to cohort 4, 15mg capsule, without modifications. This recommendation was based on the absence of any dose limiting toxicities (DLT's). In addition, no rash was observed in any of the first 9 patients who received PAS-004. The Company has decided to add a cohort 4b to the trial, which will consist of 3 additional patients and introduce an alternate formulation which is intended for commercial use.

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea stated, "We are pleased to observe that as we continue to dose escalate, we have not yet seen rash emerge. 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. In addition, we are excited to dose patients with our potential commercial formulation."

The 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).

PAS-004 Demonstrates a Differentiated MEK Inhibitor Profile

Unlike first-generation MEK inhibitors for the treatment of NF1 that require twice-daily dosing (BID) and exhibit short half-lives (<8 hours), PAS-004 has the potential to achieve prolonged target inhibition and once-daily dosing (QD) due to its long half-life of approximately 70 hours. As disclosed previously, the PK profile shows consistent plasma levels at steady-state, as reflected by a low Cmax to Cmin ratio, potentially reducing the risks for Cmax-

related toxicity. These findings provide a compelling rationale for the advancement of PAS-004 into clinical trials for both the treatment of cutaneous and plexiform neurofibromas in NF1, cancer and other MAPK-driven opportunities. The company expects to provide additional trial updates on a periodic basis as the trial progresses.

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) 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.

Pasithea Therapeutics Contact

Patrick Gaynes
Corporate Communications
pgaynes@pasithea.com

Source: Pasithea