September 9, 2024

Pasithea Therapeutics Announces Successful Completion of PAS-004 Chronic Toxicity Studies

MIAMI, Sept. 09, 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 the successful completion of long-term chronic toxicity studies in both rats and dogs with its lead candidate PAS-004, currently being investigated in a Phase 1 clinical trial in advanced cancer patients.

Results show that once daily treatment with PAS-004 for 6-months in rats and 9-months in dogs at different dose levels confirms the observations of prior 28-day toxicity studies and indicates a similar safety profile following long-term dosing in both species. Further, the 9-month study in dogs established 0.5 mg/kg as the no adverse effect level (NOAEL) in dogs, the most sensitive species. PAS-004 demonstrated a consistent safety profile at doses that correlate with significant pathway engagement and will likely produce significant pERK reduction when dosed below the NOAEL. Completion of this milestone is planned to support chronic patient dosing.

For the chronic toxicity studies, PAS-004 was administered in crystalline form and demonstrated a similar adverse event profile and equivalent NOAEL in dogs as compared to the original amorphous formulation. The Company is using a crystalline form of PAS-004 in its human clinical trials.

"It is our belief that the ability to titrate to and obtain sustained Mitogen Associated Protein kinase (MAPK) pathway suppression over a prolonged period will lead to enhanced efficacy with a more manageable side effect profile and less toxicity than that observed with other MEK inhibitors. The results of these long-term chronic toxicity studies further demonstrates PAS-004 safety profile and highlight PAS-004's potential as a best-in-class MEK inhibitor. We look forward to sharing additional data on PAS-004, including initial interim pharmacokinetic (PK) and pharmacodynamic (PD) data from our first-in-human Phase 1 clinical study later this quarter." commented Dr. Tiago Reis Marques, CEO of Pasithea.

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 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 and 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 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