May 28, 2024

Pasithea Therapeutics to Present New Preclinical Data Showing PAS-004 Strongly Inhibits NRAS Cancer Cell Lines and Demonstrates Superior Activity in Xenograft Studies at 2024 ASCO Annual Meeting

-- PAS-004 inhibition of in vitro NRAS cell lines does not plateau in contrast to approved MEK inhibitors --

-- PAS-004 inhibition of in vitro NRAS cell lines is greater than selumetinib and binimetinib and similar to trametinib --

-- PAS-004 shows superior activity versus selumetinib and binimetinib in NRAS xenograft tumor models --

-- Poster presentation on Saturday, June 1, 2024 at the ASCO Annual Meeting --

SOUTH SAN FRANCISCO, Calif. and MIAMI, May 28, 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, announced today the publication of data showing PAS-004 strongly inhibiting NRAS mutant cancer cell lines with IC50 values ranging from 0.024 to 0.306 μM. Maximal growth inhibition of >50% was achieved by PAS-004 in more cell lines than binimetinib and selumetinib. In addition, PAS-004's cell line inhibition was comparable to trametinib in 5 cell lines tested but, in contrast to trametinib, PAS-004 did not reach a plateau.

The results will be presented at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2024, in a poster session from 9:00 am - 12:00 pm CDT in Chicago, IL.

"We are excited to show new preclinical data showing enhanced potency of PAS-004 when compared to approved agents, with the potential for less frequent dosing which may lead to better tolerability and compliance." said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "We believe this emerging profile hits the sweet spot balancing pharmacokinetics (PK), pharmacodynamics (PD) and tolerability and making PAS-004 an ideal candidate for the treatment of cutaneous and plexiform NF1 as well as a potential candidate for treatment of various cancers. We are looking forward to the initial readout of our Ph1 clinical trial."

PAS-004 is the first macrocyclic MEK inhibitor to enter human clinical trials, with an expected

extended half-life which may provide better compliance rates, as well as improved efficacy in NF1. Macrocycles are known to exhibit stronger binding, better solubility and longer half-life with more selectivity and less off target effect as compared to acyclic small molecules.

Presentation and poster details

Title: PAS-004: A novel macrocyclic MEK inhibitor to inhibit cancer cell growth in vitro and tumor growth in mouse xenograft studies.
Presenting author: Graeme Currie, PhD
Session: Poster Session – Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
Date and Time: 6/1/2024, 9:00 AM – 12:00 PM CDT

About PAS-004

PAS-004 is a small molecule allosteric inhibitor of MEK 1/2, which are dual-specificity protein kinases, in the MAPK signaling pathway. The MAPK pathway has been implicated in a variety of diseases, as it functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that, when abnormally activated, are critical for the formation and progression of tumors, fibrosis and other diseases. MEK inhibitors block phosphorylation (activation) of extracellular signal-regulated kinases (ERK). Blocking the phosphorylation of ERK can lead to cell death and inhibition of tumor growth. Existing FDA approved MEK inhibitors are marketed for a range of diseases, including certain cancers and neurofibromatosis type 1 (NF1). We believe these MEK inhibitors suffer from certain limitations, including known toxicities. Unlike current FDA approved MEK inhibitors, PAS-004 is macrocyclic, which we believe may lead to improved pharmacokinetic and safety (tolerability) profiles. Cyclization offers rigidity for stronger binding with drug target receptors. PAS-004 was designed to provide a longer half-life with what we believe is a better therapeutic window. Further, we believe the potency and safety profile that PAS-004 has demonstrated in preclinical studies may also lead to stronger and more durable response rates and efficacy, as well as better dosing schedules. PAS-004 has been tested in a range of mouse models of various diseases and has completed preclinical testing and animal toxicology studies. Additionally, PAS-004 has received orphan-drug designation from the FDA for the treatment of NF1.

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, 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 Form 10-K, Form 10-Q and 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