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Pasithea Therapeutics Announces Invention of Crystalline Form of PAS-004; Establishes Strengthened Intellectual Property (IP) Position

-- Polymorph and Stereoisomer Patents when Issued Extend Portfolio to at least 2045 --

-- Polymorph and Stereoisomer Patent Filings Continue to Expand Patent Portfolio --

SOUTH SAN FRANCISCO, Calif. and MIAMI, Jan. 08, 2024 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a clinical stage biotechnology company focused on the discovery, research, and development of innovative treatments for Central Nervous System (CNS) disorders, today announced the invention of a crystalline form of PAS-004 which is captured in polymorph and stereoisomer patent filings that when issued we believe will extend patent protection to at least 2045.

Chief Development Officer Dr. Graeme Currie stated, "Through the invention of the crystal structure for PAS-004 and subsequent patent filings, we are pleased to extend and strengthen the PAS-004 patent portfolio which we believe extends current protection from 2032 to at least 2045. We worked closely with Jones Day, a top global law firm with a premier IP biotech practice, to reach this important milestone."

Chief Executive Officer Dr. Tiago Reis Marques added, "Through additional chemistry, manufacturing, and controls (CMC) development we believe that we continue to increase the value of PAS-004. We are pleased that our upcoming phase 1 dose escalation trial will utilize the newly invented crystalline drug substance."

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, including, without limitation, statements about PAS-004, including the Company’s ability to increase its value and to extend its patent protection, 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, without limitation, the Company’s ability to increase the value of PAS-004 and to extend its patent protection, 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. 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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