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Pasithea Therapeutics Announces Completion of GMP Manufacturing for PAS-004

-- Represents the final step before submission of Investigational New Drug (IND) application to FDA, expected in the second half of 2023 --

PALO ALTO, Calif. and MIAMI, June 29, 2023 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a biotechnology company focused on the discovery, research, and development of innovative treatments for central nervous system ("CNS") disorders, today announced it has successfully completed manufacturing of GMP-compliant Phase 1 clinical supplies of the active pharmaceutical ingredient ("API") of its lead product candidate PAS-004, a next-generation macrocyclic MEK Inhibitor.

GMP-compliant manufacturing of API was the final step needed to support the Investigational New Drug ("IND") application that the Company expects to file with the U.S. Food and Drug Administration ("FDA") in the second half of 2023. The Company intends to utilize this supply of PAS-004 for its upcoming Phase I clinical trial.

Dr. Tiago Reis Marques, Pasithea's Chief Executive Officer, commented "We are pleased to have reached this milestone efficiently and on time. We remain on track with our development plan for PAS-004 and look forward to our IND submission, which we intend to follow with the initiation of our first-in-human Phase 1 clinical trial. Based on preclinical testing, we believe that PAS-004 may differentiate in the clinic by virtue of a PK profile enabling the potential for once a day dosing. From our consultations with KOLs we believe a once a day dosing regimen may become the preferred treatment option for Neurofibromatosis type 1, or NF1."

Dr. Graeme Currie, Pasithea's Chief Development Officer, stated "Pasithea acknowledges our exceptional partnership with WuXi STA, a subsidiary of WuXi AppTec, for its chemistry, manufacturing, and controls (CMC) services. We are grateful to WuXi STA for its expertise throughout the process, development and manufacturing of the API. The collaboration with WuXi STA has been instrumental in enabling Pasithea to achieve this critical milestone and we believe lays a strong foundation for the continued development of PAS-004."

Following the anticipated submission of the IND application with the FDA, Pasithea plans to initiate a Phase 1 clinical trial in healthy volunteers by the end of 2023 with clinical results, including pharmacokinetic, pharmacodynamic and safety data, anticipated in the first half of 2024.

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 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 to support an IND application with the FDA that we plan to submit in the second half of 2023. Additionally, PAS-004 has received orphan-drug designation from the FDA for the treatment of NF1.

About Pasithea Therapeutics Corp.

Pasithea Therapeutics is a biotechnology company primarily 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), Amyotrophic Lateral Sclerosis (ALS) and Multiple Sclerosis (MS).

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 the Company’s plans for filing an IND application with the FDA, the initiation and anticipated results of a Phase 1 clinical trial for PAS-004, and treatment options for Nerufibromatosis type 1, as well as other statements with respect to the Company’s plans, assumptions, expectations, beliefs and objectives with respect to product development, 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 timing of the Company’s IND submission and planned clinical trials for PAS-004; the

ability of the Company's clinical trials to demonstrate the safety and efficacy and other positive results of PAS-004; and other 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.

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