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Pasithea Therapeutics Signs CMC Development and Manufacturing Agreement for the Production of PAS-004

-- Plans to Initiate a Phase 1 Clinical Trial in the U.S. for Neurofibromatosis Type 1 (NF1) in 2H 2023 --

MIAMI BEACH, Fla., Jan. 18, 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 its contract with WuXi STA, a subsidiary of WuXi AppTec, to manufacture the active pharmaceutical ingredient ("API") for Pasithea's macrocyclic, next-generation MEK Inhibitor, PAS-004 (formerly CIP-137401).

After the completion of the pre-clinical testing and animal toxicology studies, GMP manufacturing is our final major requirement to support the Company's Investigational New Drug ("IND") application with the U.S. Federal Drug Association ("FDA"), which is expected in the second half of 2023.

WuXi STA is recognized as an industry leader in "end-to-end" chemistry, manufacturing, and controls (CMC) services, for both API and finished dosage forms, with extensive expertise and track record for meeting global quality standards.

"We are delighted to be working with WuXi STA, one of the largest and most well-respected Contract, Development, and Manufacturing Organizations (CDMOs) in the world. We remain on track with PAS-004 development and look forward to our IND submission followed by the initiation of our Phase 1 clinical trial," commented Pasithea CEO, Dr. Tiago Reis Marques.

"WuXi STA has a proven track record of manufacturing success to FDA standards and we believe that their high-quality capabilities will support progression of our drug candidate into the clinic. PAS-004 has already received orphan drug designation from the FDA for neurofibromatosis 1, and we plan to start our phase 1 clinical trial in the second half of 2023," stated Dr. Graeme Currie, Chief Development Officer of Pasithea.

About PAS-004

PAS-004 is a small molecule allosteric inhibitor of MEK 1/2 in the Ras-Raf-MEK-ERK signaling pathway, which plays critical roles in the regulation of diverse cellular activities, including cell proliferation, survival, differentiation, and motility.

Existing MEK inhibitors are marketed and being tested for a range of diseases providing evidence for the value of regulating MEK as a drug target, however, they suffer from limitations. Unlike other MEK inhibitors, PAS-004 is macrocyclic, which displays improved drug-like properties, such as optimal pharmacokinetic, safety (tolerability), and potency

profiles that offer promising potential benefits over other MEK inhibitors. Macrocycles are large cyclic molecules that can bring increased potency, metabolic stability, and oral bioavailability. Cyclization offers rigidity for stronger binding with drug target receptors. PAS-004 was developed to limit metabolic liabilities and overcome the limited exposure and stability of known MEK inhibitors. PAS-004 has displayed efficacy in various animal models and has completed pre-clinical testing and animal toxicology studies to support an IND application with the FDA. PAS-004 received orphan-drug designation from the FDA for the treatment of NF1.

About WuXi STA

WuXi STA (stapharma.com), a subsidiary of WuXi AppTec, is a leading pharmaceutical development and manufacturing capability and technology platform company serving the life sciences industry, with global operations across Asia, North America, and Europe. As a premier Contract Research, Development, and Manufacturing Organization (CRDMO), WuXi STA offers its worldwide partners efficient, flexible and high-quality solutions for integrated chemical, manufacturing and controls (CMC) from preclinical to commercial uses, including the development and manufacturing of small molecule, oligonucleotide, peptide and various complex chemical conjugate. For more information, please visit: http://www.STApharma.com and follow us on LinkedIn.

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. With an experienced team of experts in the fields of neuroscience and psychopharmacology, Pasithea is developing new molecular entities for the treatment of neurological disorders, including Amyotrophic Lateral Sclerosis (ALS) and Multiple Sclerosis (MS), Neurofibromatosis type 1 (NF1) and Noonan syndrome.

Forward Looking Statements

This press release contains statements that constitute “forward-looking statements.” 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, those set forth in the Company’s filings 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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Source: Pasithea