May 14, 2025

Pasithea Therapeutics Announces Initiation of Phase 1/1B Study of PAS-004 in Adult NF1 Patients and Activation of First Clinical Trial Site

-- First patient expected to be dosed during Q2 2025--
-- Trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy in both plexiform neurofibromas and cutaneous neurofibromas --
-- Starting dose of 4mg tablet QD (once daily) --
-- First trial site in Australia. Four additional sites planned for Australia, South Korea, and U.S. –
-- Australian R&D Tax Incentive refund of up to 48.5% of eligible study-related costs expected --

MIAMI, May 14, 2025 (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 today announced initiation of its Phase 1/1b open label study to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of PAS-004, in adult participants with neurofibromatosis type 1 (NF1) with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas. The study will also assess preliminary anti-tumor activity and help determine a recommended dose for subsequent Phase 2 trials. Exploratory objectives include assessing the effects of PAS-004 on cutaneous neurofibromas.

The first active clinical trial site is the Royal North Shore Hospital in Sydney, Australia, which is expected to begin patient enrollment in Q2 2025. Additional clinical trial sites in Australia, South Korea, and the United States are expected to be opened in the coming months.

Pasithea has selected Novotech (Australia) Pty Limited as its clinical research organization (CRO) for this trial. The Company is conducting the study through its wholly owned subsidiary in Australia, Pasithea MacroMEK Pty Ltd, and anticipates eligibility for an Australian R&D Tax Incentive with a cash refund of up to 48.5% of the amount spent annually on eligible R&D activities (trial costs) in Australia.

Dr. Rebecca Brown, M.D., Ph.D. a member of Pasithea's Scientific Advisory Board and Associate Professor of Neuro Oncology at The University of Alabama at Birmingham commented, "I am pleased to have collaborated with the Pasithea team on the design of a comprehensive dose exploration and expansion study to assess the safety and tolerability of PAS-004 in adult NF1 patients. In addition to testing the effects of PAS-004 on plexiform neurofibromas, exploratory endpoints will also examine the effects of PAS-004 on cutaneous neurofibromas. The safety profile observed to date in advanced cancer patients is encouraging, and I look forward to seeing that profile translate to the NF1 population." Dr.

Brown added, “One of the biggest challenges in treating plexiform neurofibromas associated with NF1 is ensuring that patients remain on MEK inhibitor therapy over the long-term. Real-world data shows that a significant proportion of NF1 patients discontinue treatment due to poor tolerability, including high rates of rash and gastrointestinal side effects. PAS-004 is also given as a once daily dose that offers a more convenient regimen than current FDA-approved therapies that are dosed twice a day and which could improve patient compliance.”

Dr. Tiago Reis Marques, Pasithea’s Chief Executive Officer, said, “Following our recent financing, including the exercise of certain warrants, Pasithea is now funded to produce initial interim patient data in NF1. The initiation of this clinical trial in NF1, the initial indication we seek FDA marketing approval for, marks an important milestone for Pasithea and for patients living with NF1-related plexiform neurofibromas. Activating our first clinical trial site underscores our commitment to advancing PAS-004 as a potential best-in-class next-generation MEK inhibitor. We are encouraged by the safety and clinical data observed to date in oncology patients and are optimistic that PAS-004’s tolerability profile will extend to the NF1 population. Importantly, our existing cancer data has enabled us to begin the NF1 trial at a higher dose than originally contemplated. In addition, we anticipate meaningful cash rebates of eligible trial costs through the Australian R&D Tax Incentive, further enhancing the efficiency of this program.”

About the Phase 1/1b Clinical Trial in Adult NF1 Patients

The primary objective of the Phase 1/1b study (NCT06961565) is to evaluate the safety and tolerability of PAS-004 when administered for one 28-day treatment cycle in adult NF1 participants with at least one and up to two additional target plexiform neurofibromas (PNs) that are symptomatic and inoperable, incompletely resected, or recurrent. Secondary objectives are (i) to identify the recommended Part B dose (“RPBD”) or Maximum Tolerated Dose (MTD) of PAS-004, (ii) to characterize the PK and PD profile of PAS-004, (iii) to evaluate the preliminary efficacy of PAS-004 on target PN volume, (iv) to evaluate the preliminary efficacy of PAS-004 on the size, appearance, and associated symptoms of cutaneous neurofibromas (CNs), and (v) to evaluate the impact of PAS-004 on quality of life (“QOL”) and any physical symptoms attributed to the target PN. Experimental objectives are (i) to evaluate the impact of PAS-004 on QOL and any physical symptoms attributed to CNs, (ii) to evaluate the impact of PAS-004 on pain and function attributed to PNs, and (iii) to investigate PAS-004 effects on CN tumor cellular and molecular biology.

The trial will be conducted in two parts. In Part A, following a screening period of up to 28 days, up to 24 eligible participants will be enrolled sequentially to receive one of four planned dose levels of PAS-004 tablets (4mg, 8mg, 12 mg, 18mg) in a modified 3+3 design. Part A will identify the recommended RPBD. During Part B, up to 24 eligible participants will be enrolled in parallel to receive one of two planned dose levels of PAS-004 tablets. Participants will be dosed at the RPBD level and at a dose level below the RPBD for up to six continuous 28-day treatment cycles. Part B will identify the recommended phase 2 dose (RP2D).

The study is planned to be conducted at five clinical trial sites in Australia, South Korea and the U.S.

To learn more about the PAS-004 clinical trial in adults with NF1-associated plexiform neurofibromas, please visit www.clinicaltrials.gov.

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, RASopathies and MAPK pathway driven tumors.

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 statements regarding the Company’s ongoing Phase 1 clinical trial of PAS-004 in advanced cancer patients, the Company’s Phase 1/1b clinical trial of PAS-004 in adult patients with NF1-associated plexiform neurofibromas, and the safety, tolerability, pharmacokinetic (PK), pharmacodynamics (PD) and preliminary efficacy of PAS-004, as well as all other 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, pre-clinical 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 risks that future clinical trial results may not match results observed to date, may be negative or ambiguous, or may not reach the level of statistical significance required for regulatory approval, as well as 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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