July 31, 2025

Pasithea Therapeutics Completes Enrollment and Initial Dosing of First Cohort from its Phase 1/1b Clinical Trial of PAS-004 in Adult NF1 Patients

– Initial interim safety, tolerability, biomarker, and preliminary efficacy data expected in Q1 2026 –

MIAMI, July 31, 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 for the treatment of neurofibromatosis type 1 (NF1) and other MAPK pathway driven indications, today announced the Company has completed enrollment and initial dosing of three subjects in Cohort 1 (4mg tablet) from its ongoing Phase 1/1b multicenter, open-label clinical trial evaluating PAS-004 in adult NF1 patients with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas.

"Completion of enrollment and initial dosing of Cohort 1 marks a key milestone in our mission to develop PAS-004 as a potential best-in-class, next-generation MEK inhibitor for the treatment of NF1," stated Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "PAS-004 is a once-daily dosed MEK inhibitor in development for the treatment of NF1 patients with plexiform neurofibromas, as opposed to the current FDA-approved therapies that require twice-daily dosing. This may potentially offer a best-in-class advantage in terms of patient compliance. Based on the initial encouraging safety profile observed to date in our ongoing Phase 1 trial in advanced cancer patients, we are optimistic about the potential of PAS-004 to offer the NF1 population a better-tolerated MEK inhibitor and look forward to presenting initial NF1 proof-of-concept data in Q1 2026."

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 pharmacokinetics (PK) and pharmacodynamics (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, and 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.

About Pasithea Therapeutics Corp.

Pasithea is a clinical-stage biotechnology company primarily focused on the research and development of its lead drug candidate, PAS-004, a next-generation macrocyclic MEK inhibitor intended for the treatment of RASopathies, MAPK pathway-driven tumors, and other diseases. The Company is currently testing PAS-004 in a Phase 1 clinical trial in advanced cancer patients (NCT06299839), and a Phase 1/1b clinical trial in adult patients with neurofibromatosis type 1 (NF1) associated plexiform neurofibromas (NCT06961565).

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 ongoing Phase 1/1b clinical trial of PAS-004 in adult NF1 patients, 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 and financing 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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Source: Pasithea