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Pasithea Therapeutics Announces Amendments to Clinical Study Protocol for Phase 1/1B NF1 Clinical Trial

-- Remains on track to release interim NF1 data update in Q4 2026 --
-- Additional dose levels and longer treatment period added --

MIAMI, June 16, 2026 (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 it has amended the clinical study protocol for the Phase 1/1b trial of PAS-004 in neurofibromatosis type 1 (NF1) patients with symptomatic inoperable, incompletely resected, or recurrent plexiform neurofibroma (PN). The amendments include an update to the dose escalation part of the study (Part A) to allow for the enrollment of additional participants at two additional higher dose levels (24mg and 32mg), the ability to backfill completed dose cohorts (4mg, 8mg, 12mg and 18mg) with up to two participants, and the evaluation of intermediate dose levels.

In addition, the protocol amendments allow patients to remain on treatment for up to 18 months in Part A, and include additional MRI scans to comprehensively evaluate PN, as well as adding more detailed cutaneous neurofibroma (CN) measurements, including tumor height and volume.

Pasithea has completed enrollment and multi-cycle dosing of the initial 4mg, 8mg, 12mg and 18mg cohorts, and enrolled the 24mg cohort and an intermediate 15mg cohort.

"We believe increasing the breadth and depth of Part A of the NF1 study will help inform dose selection for Part B and our future registrational studies," said Dr. Kartik Krishnan, Chief Medical Officer, Pasithea. "I am pleased that we rapidly enrolled and dosed an additional 6 patients and that the amendments will allow us to provide more comprehensive data in 2026."

This multicenter, phase 1/1b, open-label study is divided into two parts: a dose-escalation phase (part A) and an expansion cohort phase (part B). To date, the dose-escalation phase has enrolled and dosed 18 patients with NF1.

About NF1- PN
Plexiform neurofibromas (PN) are tumors originating from the nerve sheath that grow through and around nerves and may involve multiple nerve branches. Thirty to fifty percent (30-50%) of patients with NF1 will harbor PNs, which can undergo malignant transformation. PN-related morbidities are primarily caused by the direct impact of the tumor on surrounding structures and can be life-threatening when they compress vital organs or when they become malignant.

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 patients with advanced cancer (NCT06299839), and a Phase 1/1b clinical trial in patients with neurofibromatosis type 1 (NF1)-associated plexiform neurofibromas with symptomatic and inoperable, incompletely resected, or recurrent PN (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 Reports 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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