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Pasithea Therapeutics Provides Outlook on PAS-004 Clinical Programs and Data Release Timelines

MIAMI, Jan. 13, 2026 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a clinical-stage biotechnology company developing PAS-004, a next-generation oral macrocyclic MEK inhibitor for the treatment of neurofibromatosis type 1 associated plexiform neurofibromas (NF1-PN), today provided updated timelines on its ongoing clinical trials in advanced cancer and adult NF1-PN patients.

Ongoing Phase 1/1b clinical trial in adult patients with NF1-PN (NCT06961565):

- Pasithea has completed enrollment of 12 patients through the first 4 dose cohorts (4, 8, 12 and 18 mg tablets) in Part A of the study.

- The Company plans to present data in the second half of 2026, including available efficacy data through the six-month timepoint for both plexiform and cutaneous neurofibromas. The planned data release is also expected to include safety, tolerability and pharmacokinetic (PK) data.

Ongoing Phase 1 clinical trial in advanced cancer patients (NCT06299839):

- Pasithea expects to present longer-term follow-up data from patients in Cohort 4 (15mg capsule) through Cohort 8 (45mg capsule) in the second quarter of 2026.

"2025 was a pivotal year for Pasithea, highlighted by early evidence of a differentiated safety and tolerability profile and initial signals of clinical activity in our first-in-human dose escalation advanced cancer study of PAS-004, our potentially best-in-class macrocyclic MEK inhibitor," said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "In November 2025, we announced encouraging results in patients previously treated with a MEK inhibitor, including a partial response and an initial disease control rate of 71.4% among efficacy evaluable patients with BRAF-mutated tumors and met our planned milestone of providing initial NF1-relevant data through the presentation of pharmacokinetic results in the first two cohorts of our NF1 study. We believe these findings from our advanced cancer study support the development of PAS-004 for the treatment of NF1-PN patients. Additionally, in December 2025, we successfully raised $60 million in gross proceeds through a public offering, enabling us to advance PAS-004 through several key milestones and support operations through at least the first half of 2028. We remain steadfast in our mission to deliver safe, tolerable and effective therapies to patients with significant unmet need, especially in indications requiring chronic dosing."

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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