June 30, 2026

Pasithea Therapeutics Announces Positive Interim Phase 1 Advanced Cancer Study Data Demonstrating Long-Term Safety and Tolerability, and Durable Clinical Activity in MEK/BRAF-Pretreated Patients, plus Protocol Expansion

-- Favorable Safety Profile Supports Long-Term Chronic Dosing: PAS-004 has been well-tolerated, with all treatment-related adverse events (TRAEs) being Grade 1 or 2, no observed cardiac or retinal treatment-related events, and low rates of rash and gastrointestinal toxicities

-- Protocol Amendment Extends Dose Escalation to Higher Levels: Continued dose escalation using tablet formulation to explore 18mg, 24mg, 30mg, 40mg, and up to 52mg dose levels to further characterize safety, pharmacokinetics (PK), and early efficacy signals at higher doses

-- Potential Best-in-Class MEK Inhibitor Profile Emerging: Interim PK and safety data at pharmacologically active doses support PAS-004 as a differentiated candidate with potential for long-term chronic dosing with favorable tolerability

-- Pilot Food Effect Study Initiated: An optional pilot food effect assessment has been introduced to evaluate the impact of fed vs. fasted administration on PAS-004 pharmacokinetics, to optimize long-term dosing strategy

MIAMI, June 30, 2026 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (Nasdaq: KTTA) (“Pasithea” or the “Company”), a clinical-stage biotechnology company developing PAS-004, a next-generation macrocyclic oral MEK inhibitor, for the long-term treatment of chronic diseases including the neurocutaneous manifestations of neurofibromatosis type 1 (NF1), today announced updated interim safety and clinical activity data from its ongoing first-in-human trial evaluating PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation, including patients who have failed prior BRAF/MEK inhibitor treatment (NCT06299839). The Company also announced details of its protocol amendment to extend dose escalation and initiate a pilot food effect assessment.

Dr. Kartik Krishnan, Chief Medical Officer of Pasithea, said, “The literature reports that patients with BRAF mutated cancer who progress on BRAF/MEK combination therapy have a median progression-free survival of approximately 5 months with rechallenge with BRAF/MEK combination therapy. We have observed that a number of these patients who previously progressed on prior BRAF/MEK inhibitor treatment have demonstrated stable

disease on PAS-004 for greater than six months, including two patients for over one year. We believe that this demonstrates that PAS-004 is an active agent. Importantly, we continue to be encouraged by the observed adverse event (AE) profile and the ability to maintain dosing in patients over a long period of time without discontinuations. Given that we have not reached the maximum tolerated dose (MTD) and the tolerability of the doses we have evaluated to date, we have decided to continue dose escalation in the study with the introduction of our tablet formulation, while also exploring the effect of food on the PK of PAS-004 to enhance our understanding about how best to maximize the benefit of PAS-004 in long-term chronic dosing."

Interim Phase 1 Results for PAS-004 through May 22, 2026:

- **34 patients have been enrolled and dosed**
  - Heavily pre-treated population with a median of 3 prior lines of therapy (range 1 – 8)
  - Difficult to treat diagnoses (e.g., refractory pancreatic cancer and ovarian cancer), including 12 patients with BRAF V600E mutations, 10 of whom previously progressed on BRAFi and/or BRAFi/MEKi combinations

- **Well-tolerated safety profile with long-term, once daily dosing**

  - No dose-limiting toxicities (DLTs), and no discontinuations due to TRAEs with 10 patients on study for >90 days, of which 6 patients >150 days, 4 patients >300 days, and 2 patients >365 days
  - All TRAEs were Grade 1 or Grade 2; Low cumulative rates of rash (12%) and diarrhea (6%) across all patients at all doses throughout the study, including no (0%) rash or diarrhea in the 4 patients on study >300 days and 2 patients >365 days
  - No events of retinal or cardiac toxicity

- **Disease stabilization in the refractory population (N=12)**
  - Multiple patients demonstrating durable clinical benefit and tumor shrinkage, including several MEK/BRAF-pretreated patients who have remained on study for greater than six months and two patients on study for over one year – exceeding the approximately 5-month median PFS reported in the literature for BRAF/MEK rechallenge in this setting. The final PFS data will not be known until the end of the trial.

- **Pharmacokinetics support daily dosing and exploration of higher dose levels**
  - Long half-life (approximately 60 hours)
  - Linear, dose proportional PK
  - Cmax/Cmin ratio <2, with both Cmax and Cmin above the IC50 (half-maximal inhibitory concentration) from our cellular assay at all dose cohorts

The Company plans to submit and present a more robust data set at a future scientific conference.

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 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.

Contact

Patrick Gaynes
Corporate Communications
pgaynes@pasithea.com

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