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# Pasithea Therapeutics Presents Updated Interim Data from Ongoing Phase 1 Study of PAS-004 at the ASCO Annual Meeting 2025

*-- PAS-004 demonstrates preliminary clinical activity as a monotherapy in patients with heavily pre-treated, refractory solid tumors --*

*-- One patient in cohort 4A (15mg capsule) with stage 4 BRAF-mutated melanoma, who had progressed after two prior lines of therapy, including a prior MEK inhibitor + BRAF inhibitor combination therapy, achieves over 5 months of stable disease with tumor volume reduction of -14.9% and remains on treatment --*

*-- PAS-004 pharmacokinetics profile potentially supports a prolonged target engagement at well-tolerated doses --*

MIAMI, June 02, 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 updated interim results from its ongoing dose escalation Phase 1 study evaluating PAS-004 in advanced cancer patients in a poster presentation at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting

The Phase 1 clinical trial is a multi-center, open-label, dose escalation, modified 3+3 study design to evaluate the safety, tolerability, pharmacokinetic (PK), pharmacodynamic (PD), and preliminary efficacy of PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation, or patients who have failed BRAF/MEK inhibition (NCT06299839).

As of the cut-off date of April 2, 2025, a total of 21 patients had been enrolled and received at least one dose of PAS-004 in six cohorts (Capsules: 2mg, 4mg, 8mg, 15mg, 22mg / Tablets: 4mg). The most common cancer diagnosis was pancreatic cancer (28.6%), colorectal cancer (28.6%), and melanoma (23.8%).

All treatment-related adverse events (AEs) have been either grade 1 or grade 2. No known MEK inhibitor class-related AEs such as ocular toxicities, cardiotoxicities, and skin toxicities were observed during the DLT observation period. No DLTs were reported, and dose escalation is ongoing.

Preliminary PAS-004 PK analysis suggests linear PK with an estimated half-life in excess of 60 hours. The Cmax (peak) to Cmin (trough) ratio was below 2 at steady state in all dose levels and has achieved potentially sufficient exposures for target engagement. This is supported by previously reported preliminary pERK inhibition observed in cohort 3 (8mg

capsule), with pERK inhibition of up to 91%.

PAS-004 has demonstrated a dose-dependent PK profile and preliminary clinical activity as a monotherapy in patients with heavily pre-treated, refractory solid tumors. In the efficacy evaluable population (n=16), early response evaluation reveals stable disease (SD) by RECIST 1.1 in 10 patients at some point during the trial, with progression free survival of up to 159 days and overall survival of up to 253 days. In Cohort 4A (15mg capsule), two out of three patients achieved stable disease and remain on therapy. One patient with stage 4 KRAS G12R-mutated pancreatic cancer, having progressive disease while on three prior lines of therapy, achieved a tumor diameter reduction of -9.8% and remains on study for over 5 months. The second patient with Stage 4 BRAF-mutated melanoma, having progressed on two prior lines of therapy, including a prior MEK inhibitor + BRAF inhibitor combination treatment, achieved tumor diameter reduction of -14.9% and remains on study for over 5 months.

“The interim results from our ongoing Phase 1 study are encouraging and we believe underscore the potential of PAS-004 as a best-in-class MEK inhibitor to serve patients with a broad range of MAPK pathway driven tumors,” said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. “MEK inhibitors have been a transformative class of treatment therapies and we continue to witness groundbreaking advances and new approvals with this class of drug across tumor types and mutational profiles. At ASCO 2025, over 15 data sets featuring MEK inhibitors are being presented underscoring the growing momentum in this field. Additionally, we have recently seen approval of two novel MEK inhibitors, mirdametinib and avutometinib, highlighting the continued relevance of this drug class in the past several months alone. As a macrocyclic compound, PAS-004 potentially represents a significant advancement in the MEK inhibitor field by offering high selectivity and sustained pathway suppression while maintaining good tolerability. This profile may make it optimal for both monotherapy and combination therapy, including in patients who have failed prior MEK inhibitors.”

The poster presentation will be available on the Pasithea website on the date of the poster session.

**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 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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