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Pasithea Therapeutics Announces Activation of Clinical Trial Site at University of Alabama at Birmingham for Ongoing Phase 1/1b Trial of PAS-004 in Adult NF1 Patients

Platinum sponsorship of NF Caregivers Symposium reinforces commitment to NF1 community

MIAMI, Nov. 04, 2025 (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, today announced activation of a new U.S. clinical trial site at the University of Alabama at Birmingham ("UAB") for its ongoing Phase 1/1b open-label study evaluating PAS-004 in adult patients with neurofibromatosis type 1 (NF1) with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas.

The UAB site joins the list of clinical centers participating in the Company's global Phase 1/1b trial, which is designed to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of PAS-004 in adult NF1 patients. Enrollment at the UAB site is expected to begin immediately.

"We are pleased to activate UAB as a clinical site for our ongoing Phase 1/1b PAS-004 trial," said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "UAB brings deep clinical expertise in NF1 and a strong commitment to advancing care for patients with NF1 neurofibromas. Alongside our continued engagement with the NF community, including our recent platinum sponsorship of the NF Caregivers Symposium, we remain focused on advancing PAS-004 through clinical development with urgency and purpose."

In parallel with the site activation, Pasithea will serve as Platinum Sponsor of the 2025 NF Caregivers Symposium that will be hosted at UAB on November 8, 2025. The symposium gathers caregivers, clinicians, researchers, and advocates to discuss patient care, caregiver support, emerging research, and quality-of-life considerations for families affected by NF1.

"Collaborations between academia, industry, caregivers, and patient advocates improve outcomes and support for NF1 patients," said Dr. Rebecca Brown, Director of NF Clinical Programs at UAB. "We look forward to participating in this clinical trial and supporting other activities that promote resources for the NF community."

About the Phase 1/1b Study of PAS-004

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 PK and 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 (dose escalation phase), 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, 12mg, 18mg) in a modified 3+3 design. Part A will identify the recommended RPBD. During Part B (expansion phase), approximately 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 Phase 1/1b clinical trial of PAS-004 in adult patients with NF1-associated plexiform neurofibromas, and the safety, tolerability, PK, 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 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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