November 25, 2025

Pasithea Therapeutics Announces $1 Million Award by ALS Association to Study the Efficacy, Safety, and Tolerability of PAS-004 for Treatment of ALS

-- The ALS Association is the world's leading funder of amyotrophic lateral sclerosis (ALS) research --

-- The Hoffman ALS Clinical Trial Awards Program was created to fund early- to mid-stage biomarker-driven clinical trials of novel or repurposed therapeutics for ALS --

MIAMI, Nov. 25, 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 that the ALS Association has awarded a Hoffman ALS Clinical Trial Award grant worth ~$1 million to study PAS-004 in ALS patients. The award was given to study the “Efficacy, safety and tolerability of PAS-004 for the treatment of ALS”.

“We are honored that the ALS Association recognizes the promise of PAS-004,” said Dr. Lawrence Steinman, Chairman of Pasithea. “Its support enables the initiation of the first clinical trial of PAS-004 in individuals living with ALS, which is a significant milestone for Pasithea as we look to provide proof-of-concept that PAS-004 may be the best-in-class MEK inhibitor for the treatment of many indications. I am delighted to continue working on the development of potentially effective treatments for ALS. PAS-004 targets a critical molecule in the pathophysiology of motor neuron disease and has delivered significant and promising results in the ALS gold standard SOD mouse model. PAS-004, already in the clinic for neurofibromatosis and advanced cancers, is showing a promising safety profile and initial monotherapy efficacy signal. We are excited for PAS-004 to enter the clinic for ALS, a disease in great need of advances in therapy."

“The ALS Association’s Hoffman Clinical Trial Awards Program supports early-stage clinical trials of potential new treatments that hold promise for those living with ALS,” said Dr. Kuldip Dave, Senior Vice President of Research at the ALS Association. “We are pleased to support the first dosing of PAS-004 in people living with ALS. By funding programs at this critical stage, we are working to accelerate the development of therapeutic candidates that can help make ALS a livable disease until we can cure it.”

Dr. Tiago Reis Marques, CEO of Pasithea, commented: “Inflammation and the aggregation of a protein called TDP-43 are well-recognized contributors to the development and progression of ALS. Two enzymes, mitogen-activated protein kinase (MAPK) and extracellular signal-regulated kinase (MEK), have been shown to play a role in TDP-43–related neurodegeneration and neuroinflammation, suggesting they represent promising

therapeutic targets. This Phase 1 study, awarded to a leading ALS institution in the US, will evaluate PAS-004 in twelve patients with ALS enrolled across three sequential dose cohorts and followed for approximately 28 weeks. In addition to assess safety and tolerability, the study will measure changes in the ALS Functional Rating Scale–Revised (ALSFRS-R) scores and neurofilament light chain (NfL) levels to explore potential early signals of clinical activity."

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).

About the ALS Association

The ALS Association is the largest ALS organization in the world. The ALS Association funds global research collaborations, assists people with ALS and their families through its nationwide network of care and certified clinical care centers, and advocates for better public policies for people with ALS. The mission of the ALS Association is to make ALS livable and cure it. For more information about the ALS Association, visit www.als.org.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. Over the course of the disease, people lose the ability to move, to speak, and eventually, to breathe. The disease is always fatal, usually within five years of diagnosis. Few treatment options exist, resulting in a high unmet need for new therapies to address functional deficits and disease progression.

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 (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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Source: Pasithea