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# Pasithea Therapeutics Announces Orphan Drug Designation by FDA of PAS-004 for Treatment of Amyotrophic Lateral Sclerosis (ALS)

## Orphan Drug Designation is intended to support the development of therapies for rare diseases affecting fewer than 200,000 people in the United States

MIAMI, June 02, 2026 (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 U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to PAS-004 for the treatment of Amyotrophic Lateral Sclerosis (ALS).

"ALS remains a devastating neurodegenerative disease with limited treatment options and significant unmet medical need," said Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "This designation further supports our efforts to explore the potential of PAS-004 in ALS and other serious diseases where dysregulation of the MAPK pathway may play an important role."

The FDA grants Orphan Drug Designation to therapies intended for the treatment, prevention, or diagnosis of diseases or conditions affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides several potential benefits to drug developers, including eligibility for tax credits for qualified clinical trials, exemption from certain FDA fees, and the potential for seven years of market exclusivity following approval.

In November 2025, the Company announced a $1 million grant award from ALS Association to study the efficacy, safety, and tolerability of PAS-004 for the treatment of ALS.

**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.

**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 patients with advanced cancer (NCT06299839), and a Phase 1/1b clinical trial in patients with neurofibromatosis type 1 (NF1)-associated plexiform neurofibromas with symptomatic and inoperable, incompletely resected, or recurrent PN (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 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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