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Pasithea Therapeutics Announces Grant of Rare Pediatric Disease Designation (RPDD) by FDA to PAS-004 for Treatment of Neurofibromatosis Type 1 (NF1)

Rare Pediatric Disease Designation may render Pasithea eligible to receive a Priority Review Voucher (PRV)

MIAMI, April 20, 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 Rare Pediatric Disease Designation to PAS-004 for treatment of Neurofibromatosis type-1 (NF1).

The FDA grants RPDD for serious or life-threatening diseases in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and affect fewer than 200,000 people in the U.S. There are approximately 115,000 individuals in the U.S living with NF1.

Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application (NDA) or biologics license application (BLA) for a rare pediatric disease may be eligible for a Priority Review Voucher (“PRV”) which can be redeemed to obtain priority review for a subsequent marketing application for a different product. The PRV may be sold or transferred to another sponsor. In the last 12 months, disclosed PRV sales have ranged from $150–$205 million.

“We are pleased to have received rare pediatric disease designation from the U.S. FDA for our PAS-004 program for patients with NF1,” said Dr. Tiago Reis Marques, chief executive officer of Pasithea. “This designation for PAS-004 reinforces the potential of PAS-004 to address this serious condition.”

PAS-004 has so far been granted the following FDA regulatory designations: Orphan Drug Designation, Fast Track Designation and Rare Pediatric Disease Designation.

The Company is currently conducting a Phase 1/1b multicenter, open-label, dose escalation trial of PAS-004 in adult participants with symptomatic, inoperable, incompletely resected, or recurrent NF1-PN (NCT06961565).

About NF1- PN
Plexiform neurofibromas (PN) are tumors originating from the nerve sheath that grow through and around nerves and may involve multiple nerve branches. Thirty to fifty percent (30-50%) of patients with NF1 will harbor PNs, which can undergo malignant transformation.

PN-related morbidities are primarily caused by the direct impact of the tumor on surrounding structures and can be life-threatening when they compress vital organs or when they become malignant.

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 1clinical trial in patients with advanced cancer (NCT06299839), and a Phase 1/1bclinical 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 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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