UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 20, 2025

Pasithea Therapeutics Corp.
(Exact name of registrant as specified in its charter)

Delaware	**001-40804**	**85-1591963**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1111 Lincoln Road, Suite 500 Miami Beach, Florida	**33139**
(Address of principal executive offices)	(Zip Code)

(786) 977-3380
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	KTTA	The Nasdaq Capital Market
Warrants to purchase shares of Common Stock, par value $0.0001 per share	KTTAW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD

On November 20, 2025, Pasithea Therapeutics Corp. (the "Company") issued the November 20 Press Release (as defined below). A copy of the November 20 Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

On November 21, 2025, the Company issued the November 21 Press Release (as defined below). A copy of the November 21 Press Release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

On November 24, 2025, the Company issued the November 24 Press Release (as defined below). A copy of the November 24 Press Release is furnished as Exhibit 99.3 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

On November 25, 2025, the Company issued the November 25 Press Release (as defined below). A copy of the November 25 Press Release is furnished as Exhibit 99.4 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, Exhibit 99.2, Exhibit 99.3, and Exhibit 99.4, is being furnished to the Securities and Exchange Commission (the "SEC"), and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On November 20, 2025, the Company issued a press release (the "November 20 Press Release") relating to positive interim Phase 1 data from its ongoing first-in-human clinical trial of PAS-004 in patients with advanced solid tumors driven by MAPK pathway alterations, including documented RAS, NF1 or RAF mutations, and in patients who have failed prior BRAF/MEK inhibition.

The Company released the below interim Phase 1 results for PAS-004 in the Press Release:

Initial Signals of Clinical Activity

Among 21 efficacy evaluable patients (as per RECIST1.1):

- **Partial Response:**
    - A BRAF V600E melanoma patient in Cohort 4A (15mg capsule) achieved an unconfirmed partial response with a **–31.9% tumor reduction** and remains on trial for >11 months; prior best response when treated with a MEK + BRAF combination therapy was stable disease
- **Disease Control Rate (DCR):**
    - 71.4% (5 of 7) of patients identified with BRAF-mutated tumors achieved stable disease or partial response
    - 42.8% (9 of 21) of patients achieved stable disease or partial response
- **Durable Stable Disease:**
    - A second BRAF V600E melanoma patient previously treated with MEK + BRAF combination therapy in Cohort 6 (30mg capsule) remains on trial for >6 months with a **stable disease** and tumor shrinkage of -1.6%

Safety and Tolerability

Among 27 dosed patients through the Dose Limiting Toxicity (DLT) period (Day 28) through the cutoff date of November 10, 2025:

- PAS-004, dosed once daily (QD), has been **well-tolerated across all dose levels**

- **No dose-limiting toxicities (DLTs)**, and **no discontinuations** have been reported.
- All treatment-related adverse events (TRAEs) at least possible related to PAS-004 were **Grade 1 or 2**, with limited rash (7.4%), nausea (18.5%), vomiting (14.8%), diarrhea (7.4%), and no ocular retinal abnormalities or cardiovascular toxicities observed.

Pharmacokinetics (PK)

PAS-004 has demonstrated through Cohort 6:

- **Linear PK** and **dose-proportionality**
- **PK curve with Cmax/Cmin ratio <2**, with Cmax and Cmin above the IC50 (half-maximal inhibitory concentration) from our cellular assay.
- **Long half-life (~60 hours)**
- Cohort 6 (30mg capsule) has demonstrated:
    - **AUC**: ~5,480 ng·h/mL
    - **Cmax**: 249 ng/mL
    - **Cmin**: 215 ng/mL

On November 21, 2025, the Company issued a press release (the "November 21 Press Release") relating to positive tablet PK data from the Company's 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.

Pharmacokinetics (PK)

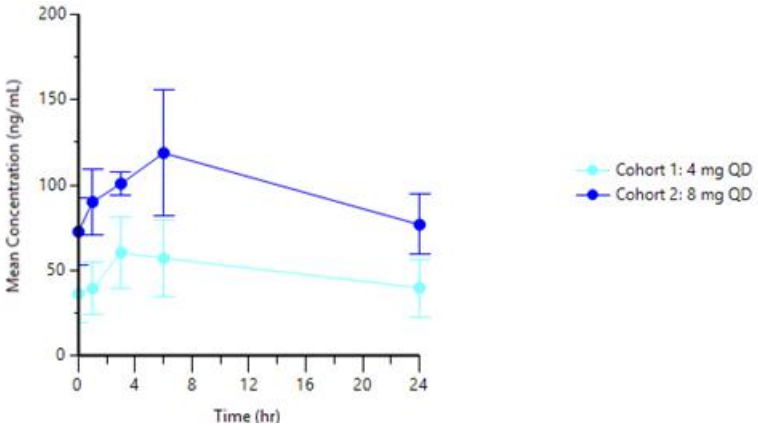
PAS-004 has demonstrated in the tablet formulation (4mg and 8mg cohorts):

- Linear PK and dose-proportionality
- PK curve with Cmax/Cmin ratio <2, with Cmax and Cmin above the IC50 (half-maximal inhibitory concentration) from our cellular assay
- Long half-life (~57 hours)
- Cohort 1 (4mg tablet) has demonstrated:
    - AUC: 1,120 ng·h/mL
    - Cmax: 58.1 ng/mL
    - Cmin: 37.6 ng/mL
- Cohort 2 (8mg tablet) has demonstrated:
    - AUC: 2,290 ng·h/mL
    - Cmax: 118 ng/mL
    - Cmin: 75.4 ng/mL

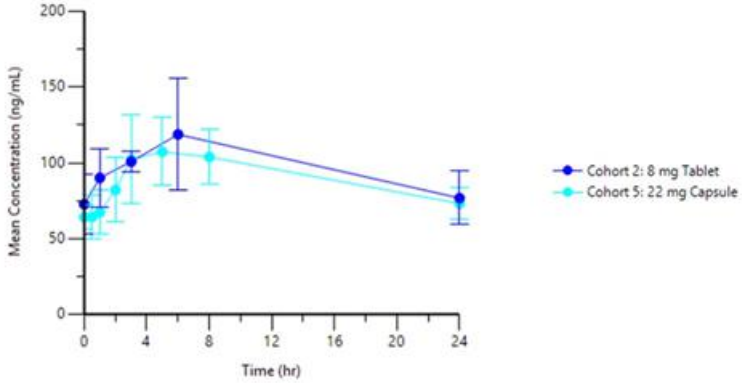
Dose normalized exposures following once daily administration of PAS-004 tablets were approximately 3-fold higher than those following administration with the capsule formulation, resulting in the 8mg tablet area under the curve (AUC) and Cmax being slightly greater than those of the 22mg capsule. The tablet formulation has demonstrated less patient variability and a similar Tmax range when compared to the capsule formulation. This is consistent with the pre-clinical evaluation of the two formulations in the dog toxicology studies.

Graph 1 below represents the tablet PK curve at steady state for the 4mg and 8mg doses and Graph 2 below represents the 8mg tablet PK curve at steady state as compared to 22mg capsule dose at steady state from our ongoing Phase 1 trial in advanced cancer patients:

Graph 1:



Graph 2:



On November 24, 2025, the Company issued a press release (the "November 24 Press Release") announcing positive safety, PK and PD data from Cohort 7 (37mg capsule) in its ongoing first-in-human trial evaluating PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation, or in patients who have failed prior BRAF/MEK inhibition.

PAS-004 has demonstrated in Cohort 7 (37mg capsule):

Safety and Tolerability Results:

- PAS-004 was safe and well tolerated with no dose limiting toxicities (DLTs), and zero treatment-related adverse events observed during the DLT period.
- After reviewing the safety data, the Safety Review Committee recommended to proceed to Cohort 8, 45mg capsule, without modification.

Pharmacodynamics (PD) Results:

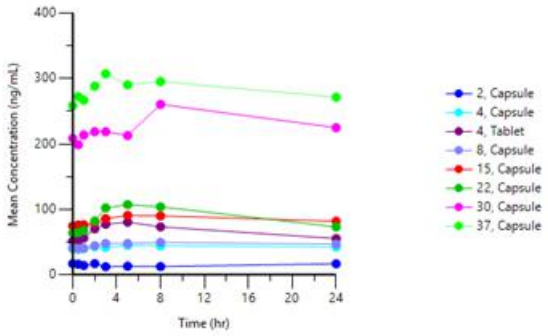
- At steady-state, patient plasma data showed PAS-004 inhibiting phosphorylated extracellular signal-regulated kinase (pERK) at a level of 80% near Cmax.
- At steady-state, patient plasma data showed PAS-004 inhibiting pERK at a level above 60% at Cmin (24-hour predose).

Pharmacokinetics (PK) Results:

- Linear PK and dose-proportionality.
- PK curve with Cmax/Cmin ratio <2.
- AUC: 6,690 ng*h/mL; Cmax: 313 ng/mL; Cmin: 260 ng/mL.

Graph 1 below represents the complete PAS-004 dose escalation curve at steady state in our ongoing Phase 1 trial in advanced cancer patients:

Graph 1:



On November 25, 2025, the Company issued a press release (the "November 25 Press Release") announcing 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."

Forward Looking Statements

This Current Report on Form 8-K 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 patients with NF1-associated plexiform neurofibromas, 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 Current Report. 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 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 Current Report, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 20, 2025.
99.2	Press Release dated November 21, 2025.
99.3	Press Release dated November 24, 2025.
99.4	Press Release dated November 25, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PASITHEA THERAPEUTICS CORP.

Date: November 25, 2025

By: */s/ Tiago Reis Marques*
Name: Tiago Reis Marques
Title: Chief Executive Officer

Exhibit 99.1

Pasithea Therapeutics Announces Positive Phase 1 Data Including Partial Response, Demonstrating Monotherapy Clinical Activity and Favorable Safety Profile for PAS-004 in Advanced Cancer Study

-- ***Evidence of Monotherapy Activity****: Partial response observed in a MEK-rechallenge 3rd-line melanoma patient with BRAF V600E mutation who remains on trial for more than 11 months --*

-- A second MEK-rechallenge 3rd-line melanoma patient with BRAF V600E mutation has achieved stable disease and remains on trial for more than 6 months --

-- Initial Disease Control Rate in efficacy evaluable patients of 71.4% with BRAF-mutated tumors: 5 of 7 patients achieved stable disease --

-- ***Favorable Safety Profile:*** *PAS-004 has been well-tolerated with all treatment-related adverse events Grade 1 or 2, no ocular or cardio toxicity, and limited rash, nausea, diarrhea, and vomiting to date --*

-- ***Favorable Pharmacokinetic (PK) Profile:*** *PAS-004 demonstrates dose-proportional PK with Cmax/Cmin ratio <2. AUC >5,400 ng·h/mL at the 30mg capsule dose (Cohort 6) --*

-- ***Potential Best-in-Class MEK Inhibitor Profile Emerging for NF1****: Interim PK and safety data at pharmacologically active doses support PAS-004 as a differentiated candidate for NF1 treatment --*

MIAMI, FL., November 20, 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 for the treatment of neurofibromatosis type 1-associated plexiform neurofibromas (NF1-PN), today announced positive interim Phase 1 data from its ongoing first-in-human trial evaluating PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation, or in patients who have failed prior BRAF/MEK inhibition.

Dr. Tiago Reis Marques, CEO of Pasithea said, "Today's updated interim results from our advanced cancer trial demonstrate the safety, PK and anti-tumor activity of PAS-004, and support its potential to be a best-in-class MEK inhibitor for the treatment of NF1-PN. Achieving a monotherapy partial response in an advanced cancer patient who had previously received a MEK + BRAF inhibitor combination therapy, and whose prior best response had been stable disease, is very promising. At our highest reported cohort (30mg capsule), we are seeing significant drug exposures (Area Under the Curve (AUC) greater than 5,400 ng·h/mL), with a relatively flat PK curve, suggesting sustained pathway inhibition. We believe this profile is well aligned with what is needed to drive meaningful clinical responses in NF1-PN patients. Published clinical data has shown that tumor response in NF1-PN is positively correlated with drug exposure (AUC), reinforcing the relevance of these findings."

Dr. Rebecca Brown, Director of the Neurofibromatosis (NF) and Schwannomatosis (SWN) Program at University of Alabama Birmingham (UAB) and Scientific Advisory Board member of Pasithea, stated: "I find it very encouraging that even when used as a monotherapy in advanced recurrent cancer patients, PAS-004 has demonstrated early signals of efficacy, but more importantly exhibited such a favorable safety profile that no dose interruptions or modifications were required. Maintaining NF1-PN patients on treatment for extended periods of time is paramount to achieving maximum tumor control. I believe that PAS-004's early efficacy signals combined with the low rate of adverse side effects may translate into better tolerability and longer time-on-treatment for plexiform neurofibromas associated with NF1, compared with current FDA-approved therapies discontinuation rates estimated as high as 40-50% before year two."

Interim Phase 1 Results for PAS-004:

Initial Signals of Clinical Activity

Among 21 efficacy evaluable patients (as per RECIST1.1):

- **Partial Response:**
    - A BRAF V600E melanoma patient in Cohort 4A (15mg capsule) achieved an unconfirmed partial response with a **–31.9% tumor reduction** and remains on trial for >11 months; prior best response when treated with a MEK + BRAF combination therapy was stable disease

- **Disease Control Rate (DCR):**
    - 71.4% (5 of 7) of patients identified with BRAF-mutated tumors achieved stable disease or partial response
    - 42.8% (9 of 21) of patients achieved stable disease or partial response
- **Durable Stable Disease:**
    - A second BRAF V600E melanoma patient previously treated with MEK + BRAF combination therapy in Cohort 6 (30mg capsule) remains on trial for >6 months with a **stable disease** and tumor shrinkage of -1.6%

Safety and Tolerability

Among 27 dosed patients through the Dose Limiting Toxicity (DLT) period (Day 28) through the cutoff date of November 10, 2025:

- PAS-004, dosed once daily (QD), has been **well-tolerated across all dose levels**
- **No dose-limiting toxicities (DLTs)**, and **no discontinuations** have been reported.
- All treatment-related adverse events (TRAEs) at least possible related to PAS-004 were **Grade 1 or 2**, with limited rash (7.4%), nausea (18.5%), vomiting (14.8%), diarrhea (7.4%), and no ocular retinal abnormalities or cardiovascular toxicities observed.

Pharmacokinetics (PK)

PAS-004 has demonstrated through Cohort 6:

- **Linear PK** and **dose-proportionality**
- **PK curve with Cmax/Cmin ratio <2**, with Cmax and Cmin above the IC50 (half-maximal inhibitory concentration) from our cellular assay.

- **Long half-life (~60 hours)**
- Cohort 6 (30mg capsule) has demonstrated:
    - **AUC**: ~5,480 ng·h/mL
    - **Cmax**: 249 ng/mL
    - **Cmin**: 215 ng/mL

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 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.

Pasithea Therapeutics Contact

Patrick Gaynes
Corporate Communications
pgaynes@pasithea.com

Pasithea Therapeutics Announces Positive PAS-004 Tablet Pharmacokinetic (PK) Data in Ongoing Phase 1/1b Trial in Adult NF1 Patients

-- Tablet PK exposure increases proportionally with an increase in dose --

-- More favorable PK properties in tablets enable a lower dose to achieve the same exposure as the capsule formulation, with improved predictability and reduced variability --

-- Tablet steady state showing Cmax/Cmin ratio <2 --

MIAMI, FL., November 21, 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 for the treatment of neurofibromatosis type 1-associated plexiform neurofibromas (NF1-PN), today announced positive tablet PK data from 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 (NCT06961565).

Pharmacokinetics (PK)

PAS-004 has demonstrated in the tablet formulation (4mg and 8mg cohorts):

- **Linear PK** and **dose-proportionality**
- **PK curve with Cmax/Cmin ratio <2**, with Cmax and Cmin above the IC50 (half-maximal inhibitory concentration) from our cellular assay
- **Long half-life (~57 hours)**

- Cohort 1 (4mg tablet) has demonstrated:
    - **AUC**: 1,120 ng·h/mL
    - **Cmax**: 58.1 ng/mL
    - **Cmin**: 37.6 ng/mL
- Cohort 2 (8mg tablet) has demonstrated:
    - **AUC**: 2,290 ng·h/mL
    - **Cmax**: 118 ng/mL
    - **Cmin**: 75.4 ng/mL

Dose normalized exposures following once daily administration of PAS-004 tablets were approximately 3-fold higher than those following administration with the capsule formulation, resulting in the 8mg tablet area under the curve (AUC) and Cmax being slightly greater than those of the 22mg capsule. The tablet formulation has demonstrated less patient variability and a similar Tmax range when compared to the capsule formulation. This is consistent with the pre-clinical evaluation of the two formulations in the dog toxicology studies.

Graph 1 below represents the tablet PK curve at steady state for the 4mg and 8mg doses and Graph 2 below represents the 8mg tablet PK curve at steady state as compared to 22mg capsule dose at steady state from our ongoing Phase 1 trial in advanced cancer patients:

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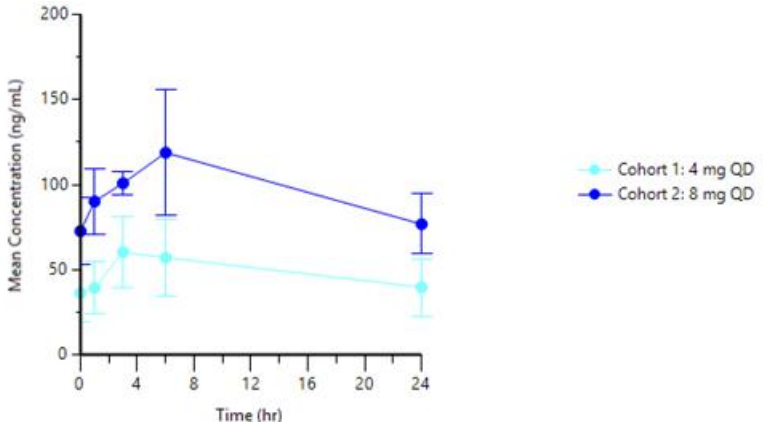
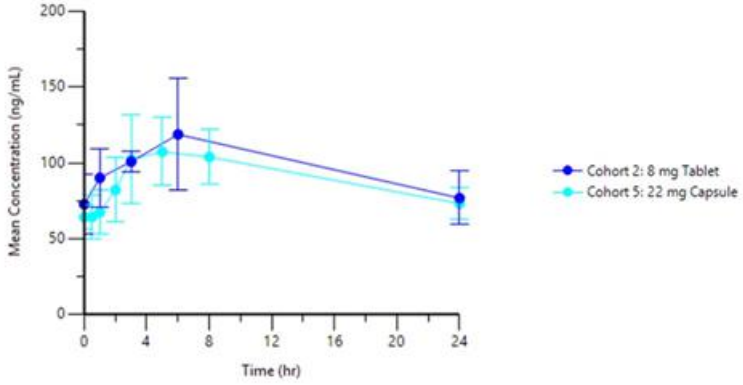


Graph 2:



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).

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Pasithea Therapeutics Contact

Patrick Gaynes
Corporate Communications
pgaynes@pasithea.com

Pasithea Therapeutics Announces Completion of Cohort 7 in Ongoing Phase 1 Trial of PAS-004 in Advanced Cancer Patients, With Positive Safety, Pharmacokinetic (PK), and Pharmacodynamic (PD) Data

-- Zero Treatment Related Adverse Events observed during Cohort 7 (37mg capsule) DLT period –

--Cohort 7 Pharmacokinetic (PK) profile continues to demonstrate dose-proportionality and Cmax/Cmin ratio <2. Achieved exposures (AUC) of 6,690 ng·h/mL --

-- Pharmacodynamic (PD) data support continuous suppression of MAPK pathway throughout the once daily 24-hour cycle –

-- Safety Review Committee recommended that trial escalate to the next dose level Cohort 8 (45mg capsule) –

MIAMI, FL., November 24, 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 for the treatment of neurofibromatosis type 1-associated plexiform neurofibromas (NF1-PN), today announced positive safety, PK and PD data from Cohort 7 (37mg capsule) in its ongoing first-in-human trial evaluating PAS-004 in patients with MAPK pathway-driven advanced solid tumors with a documented RAS, NF1 or RAF mutation, or in patients who have failed prior BRAF/MEK inhibition (NCT06299839).

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea commented, "We are highly encouraged by the initial safety data generated in Cohort 7 (37mg capsule), where zero treatment-related adverse events have been observed during the DLT period. Furthermore, PD data demonstrates the pharmacological profile we believe is necessary to achieve consistent pathway inhibition over a once daily 24-hour dosing period, while avoiding both periods of excessive suppression and periods of insufficient target engagement. We believe this balanced profile will be critical for achieving clinical efficacy while minimizing the most commonly observed adverse events associated with MEK inhibitors. We believe PAS-004 is particularly well suited for the treatment of diseases involving the MAPK pathway that require chronic dosing over long periods of time, where sustained long-term pathway suppression at safe and well-tolerated doses is required."

PAS-004 has demonstrated in Cohort 7 (37mg capsule):

Safety and Tolerability Results:

- PAS-004 was safe and well tolerated with no dose limiting toxicities (DLTs), and zero treatment-related adverse events observed during the DLT period.
- After reviewing the safety data, the Safety Review Committee recommended to proceed to Cohort 8, 45mg capsule, without modification.

Pharmacodynamics (PD) Results:

- At steady-state, patient plasma data showed PAS-004 inhibiting phosphorylated extracellular signal-regulated kinase (pERK) at a level of 80% near Cmax.
- At steady-state, patient plasma data showed PAS-004 inhibiting pERK at a level above 60% at Cmin (24-hour predose).

Pharmacokinetics (PK) Results:

- Linear PK and dose-proportionality.
- PK curve with Cmax/Cmin ratio <2.
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Graph 1 below represents the complete PAS-004 dose escalation curve at steady state in our ongoing Phase 1 trial in advanced cancer patients:

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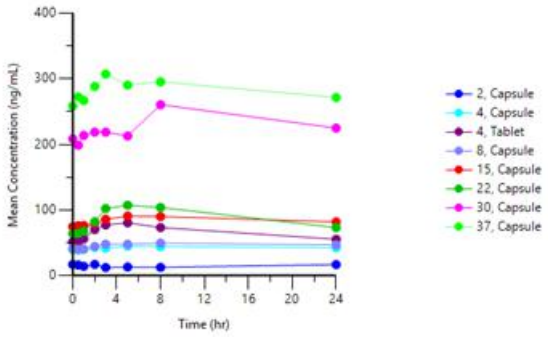

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Pasithea is a clinical-stage biotechnology company primarily focused on the research and development of its lead drug candidate, PAS-004, a next-generation macrocyclic MEK inhibitor intended for the treatment of RASopathies, MAPK pathway-driven tumors, 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 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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Exhibit 99.4

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, FL., November 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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