October 12, 2022

Pasithea Therapeutics Acquires AlloMek Therapeutics

-- Expands CNS Product Portfolio with Addition of CIP-137401, a Macrocyclic, Next-Generation MEK Inhibitor

-- Plans to File IND Application with the FDA to Enter the Clinic in 2H 2023

-- Plans to Initiate a Phase 1 Clinical Trial in the U.S. for Neurofibromatosis Type 1 (NF1)

-- Management to Host an Investor Webcast Today at 9 a.m. ET

MIAMI BEACH, Fla., Oct. 12, 2022 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (Nasdaq: KTTA) ("Pasithea" or the "Company"), a biotechnology company focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders, today announced that it acquired AlloMek Therapeutics, LLC ("AlloMek"), a privately-held biotechnology company. AlloMek's lead therapeutic candidate, CIP-137401, is a potential best-in-class macrocyclic mitogen-activated protein kinase kinase 1/2 (MEK) inhibitor for use in a range of CNS-related indications, including neurofibromatosis type 1 (NF1) and Noonan syndrome, as well as potential synergy with our existing multiple sclerosis (MS) development program. The closing of the acquisition occurred on October 11, 2022.

CIP-137401 is a small molecule allosteric inhibitor of MEK 1/2, a key kinase in the Ras-Raf-MEK-ERK signaling pathway. Existing MEK inhibitors are marketed for a range of diseases, providing evidence for the value of regulating MEK as a drug target, however, they suffer from limitations. Unlike other MEK inhibitors, CIP-137401 is macrocyclic, which displays improved drug-like properties, such as an optimal pharmacokinetic (PK), safety (tolerability) and potency profile, offering potential benefits over other MEK inhibitors. CIP-137401 was designed to limit toxicities and overcome poor pharmacokinetic profiles such as short half-lives and the formation of major metabolites, which result in the limited exposure and stability of known MEK inhibitors.

"The acquisition of AlloMek represents the successful continuation of our business development strategy. Expanding our CNS-focused drug development pipeline with near-term clinical opportunities addressing rare RASopathies positions us for long-term growth opportunities and potential synergies with our existing tolerizing program, which we believe will yield the greatest results for patients, the healthcare community and stockholders," stated Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea. "CIP-137401 was designed to impart optimum drug-like properties potentially allowing for higher exposure, improved efficacy and less frequent dosing which can drive better outcomes as well as improved patient compliance to address issues with existing MEK inhibitors. In addition, we would like to welcome the venture capital firm Connecticut Innovation Fund (CI) to our stockholder registry as a long term focused institutional shareholder who has supported the

development of CIP-137401."

CIP-137401 has displayed efficacy in a range of mouse models of various diseases and has completed pre-clinical testing and animal toxicology studies to support an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA). CIP-137401 has already received orphan-drug designation from the FDA for NF1. The Company plans to initially focus clinical development of CIP-137401 on NF1 followed by Noonan syndrome, both rare diseases with significant unmet clinical needs.

Dr. Marques added, "We look forward to bringing CIP-137401 into the clinic rapidly. We currently anticipate filing an IND in the second half of 2023 following good manufacturing practice (GMP) manufacturing of CIP-137401, which is needed for the IND-submission, and initiation of human clinical trials. Our clinical strategy is to pursue the development of CIP-137401 in NF1 followed by Noonan syndrome, which may offer the potential for a rare pediatric disease priority review voucher (PRV) from the FDA."

Dr. Uday Khire, Chief Executive Officer of AlloMek, noted, "We are excited to work with the esteemed team at Pasithea to get CIP-137401 into patients. We strongly believe in our lead molecule, CIP-137401, which has shown a unique combination of potency, tolerability and PK profile in preclinical settings and could prove to be a sweet spot among MEK inhibitors."

"We have worked with the drug candidate in our laboratory in a mouse model of a rare inherited heart disease with increased cardiac ERK activity," added Howard J. Worman, M.D., Professor of Medicine and Pathology and Cell Biology at Columbia University and Chair of AlloMek's Scientific Advisory Board. "In our model, CIP-137401 was very effective in controlling cardiac fibrosis, extremely potent in reducing tissue ERK activity *in vivo* and well-tolerated by the animals."

Lawrence Steinman MD, Professor of Neurology and Neurological Sciences at Stanford University and Chairman of the board of directors at Pasithea, concluded, "AlloMek's programs are potentially transformative for unmet needs in neurologic diseases, including NF1 and Noonan syndrome and may synergize with Pasithea's program in MS. Pasithea has experimental data on tolerizing the immune system to unwanted responses to a molecule called GlialCAM, which is similar (molecular mimicry) to Epstein-Barr virus and to members of the Poxvirus family. Published research in *Nature* showed that kinases are critical for facilitating pathological cross-reaction by adding phosphate residues (phosphorylation) to key amino acids. CIP-137401 has the potential to block phosphorylation of the molecular mimic, and by doing so, help to ameliorate the pathology that triggers MS."

Transaction Overview:

Pasithea acquired all of the issued and outstanding equity interests in AlloMek in exchange for a $1.05 million upfront cash payment and the issuance of 2,700,000 shares of restricted common stock plus 5-year warrants to acquire 1,000,000 shares of common stock at an exercise price of $1.88 per share. Pasithea is also obligated to make certain clinical and regulatory event-driven milestone payments, as well as low-to-mid single digit escalating royalties on net sales.

For a more detailed description of the terms of the AlloMek acquisition and the related definitive agreement, please see the Company's Current Report on Form 8-K to be filed with

the U.S. Securities and Exchange Commission.

Conference Call Information:

Pasithea will host a conference call and live audio webcast today, October 12, 2022, at 9 a.m. ET, to discuss the acquisition of AlloMek and provide a strategic outlook for the Company. Interested participants and investors may access the conference call by using the following URL.

- https://event.choruscall.com/mediaframe/webcast.html?webcastid=lJsMuWAK

An audio webcast of the conference call will be accessible via the Investors section of our website, www.pasithea.com. An archive of the webcast will remain available for 90 days following this event.

About CIP-137401

CIP-137401 is a small molecule allosteric inhibitor of MEK 1/2 in the Ras-Raf-MEK-ERK signaling pathway, which plays critical roles in the regulation of diverse cellular activities, including cell proliferation, survival, differentiation, and motility. Existing MEK inhibitors are marketed and being tested for a range of diseases providing evidence for the value of regulating MEK as a drug target, however they suffer from limitations. Unlike other MEK inhibitors, CIP-137401 is macrocyclic, which displays improved drug-like properties, such as an optimal pharmacokinetic, safety (tolerability) and potency profile, offering potential benefits over other MEK inhibitors. Macrocycles are large cyclic molecules that can bring increased potency, metabolic stability, and oral bioavailability. Cyclization offers rigidity for stronger binding with drug target receptors. CIP-137401 was developed to limit metabolic liabilities and overcome the limited exposure and stability of known MEK inhibitors. CIP-137401 has displayed efficacy in a range of animal models and has completed pre-clinical testing and animal toxicology studies to support an IND application with the FDA. CIP-137401has received orphan-drug designation from the FDA for NF1.

About Neurofibromatosis type 1

NF1 is part of a group of conditions known as neurocutaneous disorders that affect the skin and the nervous system. NF1 causes tumor growth along nerves in the skin, brain, near the spinal cord and other parts of the body. These tumors are usually benign (non-cancerous), however they cause a range of symptoms with varying severity among affected people. People with NF1 typically have problems with their bones, eyes and nervous system, as well as other complications, including high blood pressure, learning disabilities, attention deficit hyperactivity disorder (ADHD), seizures and speech problems. Further, some people with NF1 develop cancerous tumors that grow along nerves and are at a higher risk of developing other forms of cancer. NF1 accounts for approximately 90% of all neurofibromatosis cases and occurs in about 1 in 3,000 births. There is no known cure for NF1 and treatment options vary. Selumetinib (Koselugo^{TM}), a MEK inhibitor marketed by Alexion Pharmaceuticals, Inc., an AstraZeneca group of companies, is the only FDA-approved prescription medicine used to treat children 2 years of age and older with NF1 who have plexiform neurofibromas that cannot be completely removed by surgery.

About Noonan syndrome

Noonan syndrome, a genetic disorder, is part of a group of related conditions, collectively known as RASopathies that are associated with genes involved in the Ras-Raf-MEK-ERK cell signaling pathway. Noonan syndrome prevents normal development in various parts of the body and can affect a person in a wide variety of ways, including unusual facial characteristics, short stature, heart defects, growth and muscular skeletal issues, learning disabilities and possible developmental delays. Noonan syndrome occurs in approximately 1 in 1,000 to 2,500 people, and approximately 60% of cases involve gene mutations in the Ras-Raf-MEK-ERK signaling pathway. There is no known cure for Noonan syndrome and treatment options vary, including surgery and growth hormones.

About Pasithea Therapeutics Corp.

Pasithea Therapeutics is a biotechnology company primarily focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders. With an experienced team of experts in the fields of neuroscience and psychopharmacology, Pasithea is developing new molecular entities for the treatment of psychiatric and neurological disorders, including Amyotrophic Lateral Sclerosis (ALS) and Multiple Sclerosis, Neurofibromatosis type 1 and Noonan syndrome.

Forward Looking Statements

This press release contains statements that constitute “forward-looking statements.” 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, without limitation, those set forth in the Company’s filings 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 release, except as required by law.

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