

August 11, 2022



Pasithea Therapeutics Announces Results of Preclinical Study Demonstrating Tolerizing Vaccine Efficacy in Relapsing-Remitting Model of Multiple Sclerosis

- PAS002 is a proprietary DNA tolerizing vaccine construct encoding GlialCAM --
- PAS002 effectively reduces disease severity, delays onset of illness, while also reducing relapse severity --
- GlialCAM fragment is present in monkeypox virus, supporting a potential role in current vaccine development --

MIAMI BEACH, Fla., Aug. 11, 2022 (GLOBE NEWSWIRE) -- Pasithea Therapeutics Corp. (Nasdaq: KTTA) ("Pasithea" or the "Company"), a biotechnology company focused on the discovery, research and development of new and effective treatments for psychiatric and neurological disorders, today announced positive results from a preclinical proof of concept study of PAS002, its tolerizing vaccine program in multiple sclerosis ("MS").

Earlier this year, a [study](#) in *Nature*, the world's leading science journal, showed that a molecule called GlialCAM found in the brain's white matter is attacked in MS. GlialCAM shares a component of its protein structure that mimics an identical component of the Epstein Barr Virus ("EBV") Nuclear Antigen-1, which plays a critical role in triggering MS.

In this proof of concept study, relapsing paralysis was established in a mouse model of relapsing-remitting experimental autoimmune encephalomyelitis ("EAE"), the standard animal model of MS. In three groups, a proprietary DNA cassette was engineered to encode GlialCAM and injected to potentially block acute disease and its relapse. These DNA molecules were designed to protect against paralytic disease by tolerizing the immune system so it would not attack myelin in the brain and spinal cord. The engineered DNA molecule creates tolerance, working like an 'inverse vaccine', and was administered intramuscularly at days 0, 3, 7, 10, and 14. The study had a standard duration of 32 days.

The data showed that the engineered DNA plasmids provide a high level of efficacy in reducing disease severity and incidence of relapse when administered prophylactically in the EAE model, a widely used relapsing-remitting model of MS.

Key findings from the study include:

- treatment with a DNA tolerizing 'inverse vaccine' delayed the onset of paralysis when compared to vehicle ($p < 0.001$);
- a statistically significant reduction in disease severity, when compared to vehicle ($p = 0.002$);
- a statistically significant reduction in relapse severity, when compared to vehicle ($p < 0.001$);

- treatment with a DNA vaccine prevented disease in approximately 50% of the mice, when compared to vehicle ($p=0.004$).

The study was conducted at Hooke Laboratories, an independent full-service Contract Research Organization with deep experience in the EAE animal model of MS.

“The results of this study show that this technology has the potential to tolerize to GlialCAM, a myelin molecule that has molecular similarity to the Epstein Barr Virus that triggers MS,” stated Pasithea’s Chairman, National Academy of Sciences Professor Lawrence Steinman, a world recognized leading authority in MS. Prof. Steinman’s research led to the development of the drug Tysabri, which is approved to treat patients with MS and Crohn’s disease. “Remarkably, the piece of GlialCAM protein shared between EBV and white matter in the brain is also found in the pox viruses, including monkeypox. Monkeypox is rarely associated with brain inflammation, and this new technology may prove useful as a treatment for brain inflammation caused in certain viral infections.”

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea, stated, “We’re thrilled with the strong preclinical efficacy data shown in this study. Although early stage, we believe these results demonstrate the promise and validity of our tolerizing approach, which is built on recent data on the biological mechanism linking infection with EBV with the development of MS. We have filed a provisional patent application and we will continue to rapidly pursue the PAS002 drug development program.”

The Company plans to present data from this study, including histology data and plasma inflammatory markers, in future major international conferences, and also to submit full data for peer-review publication.

About Multiple Sclerosis

Multiple Sclerosis (“MS”) is a chronic and potentially disabling autoimmune disease, and the most common neurodegenerative disease of the central nervous system in young adults. The pathological hallmark of MS is the formation of demyelinating lesions in the brain and spinal cord, with the immune system attacking the myelin sheath that normally protects nerve fibers in the brain, spinal cord, and optic nerve. There are now 2.8 million people worldwide who have MS, and every five minutes, someone, somewhere in the world is diagnosed with this disorder. While there is no way to predict with any certainty how an individual’s disease will progress, four basic MS disease courses (also called types or phenotypes) have been defined: clinically isolated syndrome, relapsing remitting, secondary progressive and primary progressive. The most common affecting around 85 per cent of everyone diagnosed with MS is relapsing remitting MS (RRMS). It means that symptoms appear (a relapse), and then fade away, either partially or completely (remitting).

ABOUT PAS002

PAS002 is an engineered DNA plasmid designed to tolerize the immune system to GlialCAM.

About Pasithea Therapeutics Corp.

Pasithea Therapeutics Corporation is a U.S. biotechnology company focused on the

discovery, research and development of new and effective treatments for psychiatric and neurological 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. Pasithea is also focused on addressing the needs of patients currently suffering with mental illness by providing access to IV ketamine infusions both in clinics and in-home settings.

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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Source: Pasithea