



ATAI Life Sciences Announces Neuronasal Completes Pilot Study, Receives IND Clearance to Continue into Phase I Trials of mTBI Therapeutic

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NEW YORK, Oct. 27, 2020 /PRNewswire/ -- [ATAI Life Sciences](#) ("ATAI" or the "Company"), a global biotechnology company developing psychedelic and non-psychedelic compounds for various mental health indications, today announced that Neuronasal Inc. ("Neuronasal") has completed its pilot study intended to show nose to brain delivery of N-acetylcysteine (NAC) in healthy volunteers. Additionally, Neuronasal has been granted Investigational New Drug (IND) clearance by the FDA to continue phase I clinical trial development in partnership with ATAI.

Concussions and other forms of mTBI represent a significant unmet medical need. With no currently approved treatments, patients often suffer acute symptomatology including headache, nausea, fatigue, depression, anxiety and irritability. In fact, approximately half of the 2.5 million people who are concussed every year in the United States alone develop long-term cognitive impairment. Also, the ongoing NINDS-funded TRACK-TBI initiative has recently revealed that concussion is associated with substantial increases in the rates of major depressive disorder, post-traumatic stress disorder, and other psychiatric and non-psychiatric conditions.

Typically, concussions are the result of physical trauma that disrupts brain tissue and blood supply, followed by focal vascular leakage, inflammation, the formation of reactive oxygen species (ROS) and the release of excessive amounts of glutamate. This, in turn, exhausts the pool of intracellular glutathione in brain and induces glutamate-mediated neuro-excitotoxic damage. In more severe cases, neuronal atrophy and necrosis can occur as well.

Neuronasal's potentially ground-breaking proprietary treatment includes the intranasal delivery of low doses of N-acetylcysteine (NAC) to patients with acute mild traumatic brain injury (mTBI). NAC is a well-established compound that has been used safely for decades, mostly as a mucolytic and to treat acute paracetamol intoxication. NAC is stimulating the synthesis of glutathione that is the most abundant endogenous antioxidant, known to prevent oxidative damage to cellular components. In addition, NAC itself has direct antioxidant, anti-inflammatory, and free radical scavenging effects. Finally, NAC acts as an inhibitory glutamatergic modulator. All of these mechanisms are important in the context of mTBI.

NAC has the potential to disrupt the deleterious chain of events following mTBI. In soldiers exposed to explosive blast injury the probability of symptom resolution at 7 days increased from 41.9 to 86.2% when receiving NAC treatment within 24 hours post-blast.

Neuronasal's intranasal approach enables direct nose-to-brain delivery, allowing for significantly lower doses and outpatient treatment. Given its apparent efficacy in disrupting the underlying neurochemical cascade, intranasal NAC has the potential to induce a fundamental shift in the natural course of the condition for hundreds of thousands of people.

"mTBIs are more than just uncomfortable and can result in everything from depression and anxiety to cognitive decline when left untreated," said ATAI's Chief Scientific Officer, Srinivas Rao. "By developing an early intervention, we stand to disrupt a potentially disastrous disease trajectory."

"We are pleased with our pilot trial results," said Thomas Bradshaw, CEO of Neuronasal. "Our team is excited to move into Phase I clinical development with the support of the team at ATAI."

About ATAI Life Sciences

ATAI is a biotechnology company founded in 2018 in response to the clear and growing unmet needs of mental health patients worldwide. ATAI acquires, incubates and efficiently develops innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. ATAI's business model combines funding, technology, scientific and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety and therapeutic potential. By pooling resources and best practices ATAI has been able to responsibly accelerate the development of new medicines across its business entities, aiming to effectively treat and ultimately heal mental health disorders. ATAI's vision is to bridge the gap between what the mental healthcare system currently provides and what patients need. ATAI is headquartered in Berlin, with offices in New York and San Diego. For more information, please visit www.atai.life.

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