Neuronasal completes pilot study, receives IND clearance to continue into phase I trials of mTBI therapeutic
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Today, ATAI Life Sciences AG ("ATAI" or the "Company"), a global biotech platform that envisions an end to mental illnesses, and Neuronasal announced the completion of a 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 with ATAI's support.

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 a precursor of cysteine, stimulating the synthesis of glutathione which in turn 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.

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.

"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.

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.

NAC has the potential to disrupt the deleterious chain of events following mTBI. In soldiers exposed to explosive blast injury, NAC treatment, as compared to a placebo, increased the probability of symptom resolution at 7 days from 41.9 to 86.2% when administered 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.

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

Phase I clinical development continues.