



ATAI Life Sciences Partners with Neuronasal Inc. to Develop Novel Treatment for mild Traumatic Brain Injury (mTBI)

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BERLIN and WEXFORD, Pa., Jan. 6, 2020 /PRNewswire/ -- **ATAI Life Sciences AG ("ATAI" or the "Company")**, a global biotech platform that envisions an end to mental illnesses, today announced that it has partnered with Neuronasal Inc., to develop a short-term treatment for mild Traumatic Brain Injury (mTBI) or concussion.

Neuronasal's potentially ground-breaking, proprietary treatment includes the intranasal delivery of low doses of N-acetylcysteine (NAC) to patients with acute 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.

"It's clear that concussions and other mTBIs are more than just uncomfortable," said Dr. Matthias Luz, Chief Medical Officer of ATAI Life Sciences. "In the hours and days after trauma, these injuries trigger a pathophysiological cascade that can result in significant, life-limiting conditions if not adequately addressed."

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 placebo, increased the probability of symptom resolution at 7 days from 41.9 to 86.2% when administered within 24 hours post-blast.

A particular problem with the use of NAC is the blood-brain barrier which effectively shields the brain from many drugs including NAC. When administered orally, several grams of NAC are required to reach the requisite drug concentrations in brain, doses which often cause significant side effects like nausea and diarrhea. Intravenous drug administration allows for slightly lower doses but requires several days of inpatient care and often leads to dizziness and headache.

By contrast, 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.

"Neuronasal has the potential to transform the way we treat those most at risk of mTBI, with applications in sports, the military, and daily life," said Thomas Bradshaw, CEO of Neuronasal. "Unsurprisingly, we've seen incredible interest from everyone from the Department of Defense to the National Collegiate Athletic Association."

A pilot study exploring the effects of intranasal NAC administration on regional brain glutathione concentrations in healthy volunteers is expected to begin in February.

About ATAI Life Sciences

ATAI Life Sciences AG is a global biotech platform and company builder founded by Christian Angermayer. Based in Berlin, London and New York, its vision is to cure mental health disorders, enabling people to live healthier and happier lives.

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