

ATAI Life Sciences launches EmpathBio to treat post-traumatic stress disorder with novel MDMA product

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NEW YORK, Aug. 24, 2020 /PRNewswire/ -- Today, ATAI Life Sciences ("**ATAI**" or the "**Company**"), a global biotech developing psychedelic and non-psychedelic compounds for various mental health indications, announced the launch of EmpathBio, a wholly-owned subsidiary developing derivatives of 3,4-methylenedioxy-methamphetamine (MDMA) for the treatment of post-traumatic stress disorder (PTSD) and other indications.

PTSD is a chronic condition characterized by recurring and intrusive thoughts or memories. Often co-occurring with major depression, PTSD has devastating effects on all aspects of an individual's life. Indeed, one Danish study found that persons with PTSD were 13 times more likely to commit suicide than the general population.

In the US alone, an estimated 13 million people meet the criteria for a PTSD diagnosis. At present, the only FDA approved treatments for PTSD are selective serotonin reuptake inhibitors (SSRIs), namely sertraline hydrochloride (Zoloft) and paroxetine hydrochloride (Paxil). Unfortunately, not only does each come with significant side-effects, two-thirds of patients either do not response or have only a partial response to SSRIs.

MDMA itself is an amphetamine derivative that possesses complex pharmacology and is believed to act by increasing the release of monoamines like serotonin, norepinephrine and dopamine in the brain, as well as stimulating neurohormonal activity. These effects are thought to result in the anxiolytic, prosocial and empathic responses seen with MDMA administration in humans. As a result, MDMA is often classified as an entactogen rather than a typical psychedelic.

MDMA's entactogenic effects typically last approximately six hours and are hypothesized to promote a sense of psychological safety which may allow patients to more effectively address their individual traumas during psychotherapy. The derivatives of MDMA being developed by EmpathBio are expected to have similar effects.

"PTSD is a debilitating condition which affects millions worldwide," said Florian Brand, CEO of ATAI Life Sciences. "Entactogen-assisted psychotherapy promises to fundamentally change how we think about this notoriously difficult to treat disorder."

The use of MDMA for PTSD has been the subject of extensive research by the Multidisciplinary Association of Psychedelic Research (MAPS) and phase III clinical trials are ongoing. Published results from their phase II clinical trials showed that 56% of participants no longer met the criteria for PTSD two-months after the final MDMA-assisted psychotherapy session. Additionally, researchers followed up with 91 participants twelve months later and found that 67% still did not meet PTSD criteria.

EmpathBio is focused on developing MDMA derivatives with different pharmacological profiles than MDMA. The company believes that such changes may permit the entactogenic effects of MDMA to be separated from some of the known adverse effects. If successful, such an approach could help minimize some of the transient physiological changes caused by MDMA, potentially expanding the pool of PTSD patients who will be medically eligible for the therapy.

"While MDMA-assisted psychotherapy holds great promise for the treatment of PTSD, refinement of MDMA's entactogenic pharmacology could provide for a greater therapeutic index," said Glenn Short, CEO of EmpathBio. "We want to ensure that entactogen-assisted psychotherapy is available to all living with PTSD."

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About ATAI Life Sciences

Founded by visionary entrepreneur Christian Angermayer, ATAI Life Sciences AG is a global biotech platform and company builder working to address significant unmet medical needs rooted in a lack of innovation in neuropsychiatry. Based in Berlin, London and New York, its vision is to cure mental health disorders, enabling people to live healthier and happier lives. <u>www.atai.life</u>

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