

ATAI Life Sciences Announces Joint Venture with DemeRx to Develop Ibogaine For Opioid Use Disorder

January 24, 2020

BERLIN and MIAMI, Jan. 24, 2020 /PRNewswire/ -- ATAI Life Sciences AG ("ATAI" or the "Company"), a global biotech platform that envisions an end to mental illnesses, today announced an investment in two separate joint ventures (JV) with DemeRx, a clinical stage pharmaceutical company focused on developing ibogaine and noribogaine for the treatment of opioid use disorder (OUD).

OUD represents a significant unmet medical need, particularly in the United States. In 2018 alone, 2.1 million Americans met the diagnostic criteria for OUD, while 47,600 people died from opioid overdoses. Current treatment options for OUD are limited and carry risk of significant side effects and abuse potential. Overall, relapse rates across substance use disorders are estimated to be between 40 and 60%, due in part to the lack of effective therapeutics and low patient compliance.

Ibogaine is a natural indole alkaloid derived from the West African iboga plant and has previously been marketed as a stimulant and antidepressant in France under the brand name Lambarène. Known for its oneirophrenic and hallucinogenic properties, uncontrolled data from hundreds of patients suggest that ibogaine is effective as both an acute detoxifier and treatment for opioid addiction.

The largest study of ibogaine to date, an open-label case series of 102 opioid dependent and 89 cocaine dependent subjects in St. Kitts, West Indies, found that a single low, orally administered dose of ibogaine significantly reduced opioid withdrawal scores 36-hours post treatment, while also reducing the severity of cravings and depression in both cohorts. Importantly, these positive effects persisted at a one-month follow up.

"Not only were patients able to safely and successfully transition into sobriety, we found no evidence of additional abuse potential," said Dr. Deborah Mash, CEO of DemeRx and principal investigator on the St. Kitts study. "Given the limitation in currently available treatments, ibogaine represents an enormous leap forward for OUD sufferers."

While complications related to ibogaine have been documented, most such cases appear to be due to prior medical conditions or drug interaction. Of 19 recorded fatalities between 1990 and 2008, none were found to be the result of ibogaine's toxicity. Nevertheless, ibogaine therapy is contraindicated for those with cardiovascular issues, particularly in cases of prolonged QTc Interval or hypertrophic cardiomyopathy. The ibogaine JV will involve developing a treatment protocol that includes proper screening procedures, dosing guidelines, and administration best practices to ensure patient safety.

Ibogaine affects a variety of neurotransmitter systems, including serotonin, opioid, and NMDA receptors. In humans, ibogaine is metabolized into noribogaine, which may itself have applications as a follow-up or maintenance therapy; its potential as a separate treatment will be evaluated in the noribogaine JV. Although the exact mechanisms behind ibogaine's dissociative psychedelic effects are unclear, it has been speculated that the dream-like state induced in patients leads to a kind of "brain reset" that is important for the therapeutic effects observed.

Due to the extensive database for ibogaine, including a substantial amount of human data, ATAI and DemeRx plan to submit Clinical Trial Applications for a Phase II study in opioid-dependent patients.

"We are very concerned about the opioid epidemic in the United States and around the world," said Florian Brand, CEO of ATAI. "Together with DemeRx, we are committed to developing novel approaches to both treat and prevent opioid addiction."

"This addition to our platform is particularly meaningful for us because it rounds out our focus on the essentials of mental healthcare, namely depression, anxiety – and now – addiction," added ATAI founder Christian Angermayer. "Our values are aligned with the needs of underserved patients, so we see it as our responsibility to tackle the opioid crisis head on."

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. <u>www.atai.life</u>

Company Contact:

Allan Malievsky ATAI Life Sciences Phone: +1 (917) 974-1371 Email: <u>Allan@ATAI.life</u>

Investor Contact:

Allison Soss KCSA Strategic Communications Phone: +1 (212) 896-1267 Email: <u>ATAI@KCSA.com</u>

SOURCE ATAI Life Sciences

Related Links

http://www.atai.life