DemeRx Receives MHRA Approval for DMX-1002 (Ibogaine) to Commence Phase 1/2a Study as First Clinical Trial in Opioid Use Disorder in the UK

March 10, 2021

NEW YORK, March 10, 2021 /PRNewswire/ -- DemeRx IB, Inc. (DemeRx), an atai Life Sciences (atai) platform company focused on developing ibogaine for the treatment of opioid use disorder (OUD), today announced the company has approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to commence subject enrollment in a Phase 1/2a clinical trial of ibogaine HCl (DMX-1002).

Ibogaine is a naturally-occurring psychedelic product isolated from a West African shrub that has demonstrated rapid and sustained efficacy in treating OUD. This regulatory approval comes as a break-through for patients seeking to end their intractable cycle of drug dependence.

The Phase 1 portion of the MHRA approved trial will be conducted at the Manchester clinical unit of MAC Clinical Research (MAC), one of Europe's largest clinical development organizations. MAC's extensive good clinical practice experience, expertise and infrastructure will provide a platform for what is hoped to be a successful and significant trial.

"Our clinical trial authorization is a critical milestone," said Dr. Deborah Mash, CEO and President of DemeRx. "Stage 1 of the study will provide assessment of safety through the evaluation of ibogaine's potential adverse effects before we move to the proof-of-concept efficacy portion of our study in patients who seek to detoxify from opioids".

"This approval allows DemeRx to progress clinical research beyond the previously published uncontrolled studies with ibogaine into well-designed, controlled studies in support of regulatory processes," said Srinivas Rao, Chief Scientific Officer and Co-founder of atai Life Sciences. "With the initiation of this trial, we start a journey towards understanding the potential of DMX-1002, in-line with regulatory bodies. We are optimistic for the future of DMX-1002 in treating OUD – this is a great step forward for DemeRx."

"Timing could not be more important as the world faces an ever-growing opioid epidemic. Current treatment options are not highly effective; approximately 75% of patients undergoing OUD therapy experience relapse within one year of treatment," said Florian Brand, Chief Executive Officer and Co-founder of atai Life Sciences. "This approval allows DemeRx to initiate this well-designed protocol to advance our understanding of how DMX-1002 may provide patients with a potentially transformative therapy, where currently the industry has developed few treatment solutions."

About the Phase 1/2a clinical trial approval

The approval for a Phase 1/2a clinical trial will enable DemeRx to study DMX-1002 in recreational drug users before the start of Stage 2 in opioid-dependent patients. Before the start of Stage 2, the trial will pause to allow MHRA to review human safety data together with nonclinical study results.

About DemeRx, Inc. & DMX-1002

DemeRx, Inc. is a Miami-based clinical stage pharmaceutical company focused on developing ibogaine and noribogaine for the treatment of OUD. DemeRx's mission is to advance the development of potential treatments for OUD in order to prevent patient suffering, provide better treatment retention, and decrease illegal opioid use.

DemeRx is developing DMX-1002 for the treatment of OUD. DMX-1002 is a GMP drug product manufactured for human use.

Company Contacts:
Deborah C Mash PhD
CEO & Founder, DemeRx Inc.
Phone: +1(305)753-2175
Email: dmash@demerx.com

Matthias Luz MD
Executive Vice President & Chief Medical Officer
Email: mluz@demerx.com

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. atai was founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to acquiring, incubating and efficiently developing 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 profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders. atai's mission 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. For more information, please visit www.atai.life.

Investor Contact:
Greg Weaver
atai – Chief Financial Officer
Email: greg.weaver@atai.life

Media Contact:
Anne Donohoe
KCSA Strategic Communications
Phone: +1 (212) 896-1265
Email: atai@KCSA.com

SOURCE atai Life Sciences

Related Links

http://www.atai.life