



## **DemeRx Doses First Subject in Phase 1/2a Study of DMX-1002 (Ibogaine) in Opioid Use Disorder**

September 21, 2021

NEW YORK, Sept. 21, 2021 (GLOBE NEWSWIRE) -- DemeRx IB, Inc. ("DemeRx"), an atai Life Sciences (Nasdaq: ATAI) ("atai") platform company focused on developing ibogaine for the treatment of opioid use disorder (OUD), today announced that the first subjects have been dosed in a Phase 1/2a clinical trial of ibogaine HCl (DMX-1002). The trial has commenced enrollment and dosing of recreational drug users and healthy volunteers in the Phase 1 segment of the study at the Manchester clinical unit of MAC Clinical Research (MAC) in the UK, one of Europe's largest clinical development organizations.

DMX-1002 is an oral formulation of ibogaine, a naturally occurring psychedelic product isolated from a West African shrub. In previously published non-controlled studies, ibogaine has demonstrated rapid and sustained efficacy in treating OUD and has the potential to be a disease modifying treatment for this vulnerable patient population seeking to end their intractable cycle of drug dependence.

The Phase 1/2a trial is designed to assess safety, tolerability, pharmacokinetics, and efficacy, and the results will inform future studies in patients with opioid use disorder. We expect to obtain safety data from the phase 1 segment of this trial in early 2022.

"By launching the Phase 1/2a trial, we look forward to bringing important data from carefully designed, controlled studies to the existing literature on ibogaine, a compound with substantial history," said Dr. Deborah Mash, CEO and President of DemeRx. "We are hopeful that this early trial can begin to establish a safe and efficacious profile for ibogaine, so that we can potentially offer a new option for patients seeking to break free from OUD who have far too few options."

"The opioid crisis has ravaged the U.S. for over 20 years with little sign of letting up. The COVID-19 pandemic revealed the tragic vulnerability of people addicted to drugs as the CDC tallied 93,000 drug overdose deaths in 2020, a 30% increase, 70,000 of which involved opioids," added Srinivas Rao, Chief Scientific Officer and Co-founder of atai Life Sciences. "Launching our Phase 1/2a trial of ibogaine with assent of regulators, we believe is a major step towards reversing the trend of the opioid crisis."

"We strive for bold innovation to address the global crisis of mental health," said Florian Brand, Chief Executive Officer and Co-founder of atai Life Sciences. "By launching this Phase 1/2a trial, we are grateful for the work of our dedicated teams at DemeRx and atai who are committed to this ethos, striving to bring transformative treatments through rigorous testing."

### **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.

### **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 has offices in New York, London, and Berlin. For more information, please visit [www.atai.life](http://www.atai.life).

### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements, including without limitation statements regarding the initiation of the Phase 1/2a clinical trial of ibogaine HCl and future activities thereunder, the potential of DMX-1002, and similar statements of a future or forward-looking nature. Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties

that could cause actual results to differ materially from those projected, including, without limitation, the important factors discussed under the caption “Risk Factors” in atai’s prospectus pursuant to Rule 424(b) filed with the U.S. Securities and Exchange Commission (“SEC”) on June 21, 2021, as such factors may be updated from time to time in atai’s other filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof and accordingly undue reliance should not be placed on such statements. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, whether as a result of new information, future events or otherwise, other than to the extent required by applicable law.

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