



atai Life Sciences and Massachusetts General Hospital Announce Initiation of Clinical Study Investigating Neuroplasticity Biomarkers in Treatment-Resistant Depression Patients Undergoing Ketamine Treatment

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NEW YORK and BERLIN, Nov. 17, 2022 (GLOBE NEWSWIRE) -- [atai Life Sciences](#) N.V. (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced it has initiated a clinical study with [Massachusetts General Hospital](#) (MGH).

The study will utilize a neuroimaging method to identify neuroplasticity biomarkers in patients with treatment-resistant depression (TRD) undergoing intravenous (IV) ketamine treatment. The main objective of this study will be to develop a novel method to detect neuroplasticity through magnetic resonance imaging (MRI) scans, electroencephalogram (EEG) collection and clinical assessments. The study will identify changes in the brain at baseline, 24-48 hours post-treatment, and 2 weeks after ketamine administration. The availability of a validated protocol to measure structural plasticity at the neuronal level in the human brain would be a great advancement to the field of neuroplasticity research and may represent a potential tool for drug developers, researchers, and providers as an early biomarker of treatment response and efficacy.

"The study results will help guide atai's efforts to discover personalized mental health treatments. Novel imaging biomarkers during ketamine treatment will enable a deeper understanding of the therapeutic mechanisms of action (MoA) and the pathophysiology of TRD. This knowledge can potentially help improve patient outcomes by informing if and how patients are responding to treatment and eventually which patients will most benefit from treatment," commented atai's Chief Medical Officer, Rolando Gutiérrez-Esteinou, MD. "The highly experienced team and technological resources at MGH will be invaluable in this endeavor."

Nearly half of the \$350 billion spent every year in the U.S. on mental healthcare is attributable to treatment-resistant patients: those who do not experience relief from their symptoms despite multiple treatments. Treatment resistance reflects both the limitations of our currently available treatments, as well as the likelihood that these patients' brains are less capable of change in ways that improve mental health.

MGH is Harvard Medical School's largest teaching hospital. Their [Intravenous Ketamine Clinic for Depression](#) offers access to ketamine treatment for severe and refractory depression. And these new brain imaging technologies available at MGH through the support of this study will allow scientists advanced neuroimaging tools and methods to see the neuroplastic effects of fast-acting drugs like ketamine.

[Dr. Cristina Cusin](#), Associate Professor in Psychiatry at Harvard Medical School, Director of the MGH Ketamine Clinic and Psychiatrist at the Depression Clinical and Research Program, and [Dr. Susie Huang](#), Associate Professor of Radiology at Harvard Medical School and Attending Radiologist in the Division of Neuroradiology and [Athinoula A. Martinos Center for Biomedical Imaging](#) in the Department of Radiology at the Massachusetts General Hospital, will serve as co-investigators for the study.

Dr. Cusin said of the collaboration, "We are committed to providing excellent care to patients in need. A critical piece of this is conducting ground-breaking research. We look forward to embarking on this clinical study to help develop new tools to understand the biological changes occurring in depression, which, in turn, may lead to better and faster diagnosis, more personalized treatments and better outcomes."

About atai Life Sciences

atai Life Sciences is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. 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.

By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies to achieve clinically meaningful and sustained behavioral change in mental health patients.

atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. For more information, please visit www.atai.life

About Massachusetts General Hospital

Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The Mass General Research Institute conducts the largest hospital-based research program in the nation, with annual research operations of more than \$1 billion and comprises more than 9,500 researchers working across more than 30 institutes, centers and departments. In July 2022, Mass General was named #8 in the U.S. News & World Report list of "America's Best Hospitals." MGH is a founding member of the Mass General Brigham healthcare system.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things: statements regarding the trials and future activities thereunder, the potential trial success, cost and timing of development of our product candidates, including the progress of preclinical and clinical trials and related milestones; our business strategy and plans; potential acquisitions; and the plans and objectives of management for

future operations and capital expenditures. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance, or achievements to differ materially from those expressed or implied by these forward-looking statements.

The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, including without limitation: we are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts; our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability; we have never generated revenue and may never be profitable; clinical and preclinical development is uncertain, and our preclinical programs may experience delays or may never advance to clinical trials; we rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts; and a pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results. These and other important factors described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission ("SEC"), as further updated in our Quarterly Reports on Form 10-Q and subsequent filings with the SEC, from time to time, may cause our actual results, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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