atai Life Sciences Announces First Subject Dosed in Phase 1 Trial of Buccal and IV VLS-01, a Synthetic Form of DMT

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- atai has dosed the first subject in their Phase 1 single-ascending dose (SAD) trial of VLS-01 with topline results expected in H1 2023.

- VLS-01 is a synthetic form of N,N-dimethyltryptamine (DMT) under development for treatment-resistant depression (TRD) in combination with atai's digital therapeutic designed to provide contextual "(mind)set-and-setting" support to patients prior to dosing.

- Approximately one-third of people with depression are treatment resistant, totaling over 100 million people globally.

NEW YORK and BERLIN, Oct. 05, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) ("atai"), which is developing VLS-01, a form of N,N-dimethyltryptamine (DMT) for the treatment of treatment-resistant depression (TRD), announced today the dosing of the first subject in their Phase 1 SAD trial of VLS-01.

The trial is a randomized, double-blind, placebo-controlled study designed to evaluate the relative bioavailability of buccal versus IV formulations, the safety, and tolerability of VLS-01 administered by both routes, as well as pharmacodynamics of DMT using qEEG and other measures. Buccal VLS-01 is formulated to provide a psychedelic experience lasting 30 to 45 minutes, thus potentially allowing for a shorter clinic visit compared to many other psychedelic compounds that may require a patient to be monitored for four or more hours.

The trial includes the companion use of atai's IDEA-1 digital therapeutic app to provide contextual "(mind)set-and-setting" prior to dosing, as well as behavioral activation therapy, group therapy, and patient monitoring post-dosing. These behavioral assessments, in conjunction with the pharmacokinetic and safety readouts, are expected to inform the design of and doses tested in future Phase 2 clinical trials of VLS-01.

An estimated 100 million people live with TRD globally – or a third of people with depression – who are undertreated or unresponsive to available treatment options. In addition to its impact on patients, families, and caregivers, TRD significantly burdens healthcare systems and payers. Direct medical costs for TRD patients are estimated to be two times higher than for non-TRD major depressive disorder (MDD) patients, with an average of twice the number of inpatient visits and hospital stays that are over one-third longer.

"Exploring novel approaches to drug delivery can potentially simplify in-clinic administration and allow greater pharmacokinetic control of the psychedelic experience and its overall duration of hallucinogenic effects," said Srinivas Rao, Chief Scientific Officer of atai Life Sciences. "We're pleased to see this trial move forward as we establish the safety and tolerability of our compound."

"A practical approach to DMT administration would give people access not only to the pharmacological benefits of DMT but will also afford them time to explore the personal insights from their experiences with therapists," said Glenn Short, Senior Vice President, Early Development of atai Life Sciences. "Given the scale of the depression crisis, the impact on patients and families could be enormous."

atai anticipates Phase 1 topline results in H1 2023.

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

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 by Viridia Life Sciences and future activities thereunder, the potential of VLS-01, the 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”), our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as updated by our subsequent filings with the SEC, 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.

Contact Information

Investor Contact:
Stephen Bardin
Chief Financial Officer
IR@atai.life

Media Contact:
Allan Malievsky
Senior Director, External Affairs
PR@atai.life