atai Life Sciences Announces First Participant Dosed in Phase 1b Trial of VLS-01

March 4, 2024

- *The Phase 1b trial of VLS-01 investigates the pharmacokinetics, pharmacodynamics, safety and tolerability of atai's proprietary, optimized oral transmucosal formulation of DMT*

- *VLS-01 is being developed as a rapid-acting and durable antidepressant for treatment resistant depression, which affects approximately 100 million people globally*

- *VLS-01 is designed to induce a short psychedelic experience, allowing for a total in-clinic treatment of 2-hours, consistent with an established commercial paradigm in interventional psychiatry*

NEW YORK and BERLIN, March 04, 2024 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced that the first healthy participant has been dosed in the Phase 1b trial of VLS-01, an oral transmucosal film (OTF) formulation of *N,N*-dimethyltryptamine (DMT).

The Phase 1b study is designed to evaluate the relative safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of an optimized OTF formulation of VLS-01, compared to intravenous (IV) DMT. This single center, open label study is anticipated to enroll a total of 16 healthy participants. Participants will initially receive a single dose of IV DMT followed by 3 different doses of VLS-01, with a 28-day washout window between administrations. Top-line results for the Phase 1b study are expected in the second half of this year.

"I am delighted with the swift progress our team has made to commence dosing in the Phase 1b trial," said atai Co-founder and Chief Executive Officer, Florian Brand. "Our proprietary oral transmucosal formulation of DMT, VLS-01, is designed to induce a short psychedelic effect to allow for scalability and broad patient access. VLS-01 is expected to fit into an established interventional psychiatry treatment paradigm of 2 hours in the clinic and is anticipated to offer a more patient and physician-friendly experience compared to intravenous administration."

Results from the previous Phase 1 single ascending dose trial were the basis for further formulation optimization, which included the incorporation of taste masking, the addition of a backing layer, and enhancements to further increase permeability. The optimized formulation currently being tested is designed to improve PK and the patient experience ahead of moving into an anticipated Phase 2 trial with VLS-01 in TRD.

About VLS-01
VLS-01 is a proprietary OTF formulation of DMT being developed for patients living with treatment-resistant depression. Pharmacologically, DMT is a partial agonist of the 5-HT 1A/2A/2C receptors, characterized by an intrinsically short duration of psychedelic effect. Clinical evidence suggests that a single administration of IV DMT results in rapid-acting and durable antidepressant effects in patients with major depressive disorder. The company's proprietary OTF formulation is designed to eliminate the need for IV administration, provide improved PK compared to such route of administration, and maximize the therapeutic potential of a 2 hour in-clinic patient visit.

About atai Life Sciences
atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders and was founded as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to 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 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. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and the negative of these terms and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including without limitation our expectations and projections regarding the success, potential uses and timing of development of VLS-01 and related trials and studies, and our business strategy and plans.

Because forward-looking statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: clinical and preclinical development is uncertain, and our programs may experience delays or may never advance to clinical trials; our reliance on third parties to assist in conducting our clinical trials including failure by third parties to meet trial or testing deadlines; our reliance on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates; the timing and outcome of regulatory review and/or approvals; research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others; significant competition; obtaining, maintaining and protecting our intellectual property; restricted operating activity as a result of covenants in any financing arrangements; and operational activity. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described in our Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") and our quarterly reports on Form 10-Q, as may be updated by other filings we file with or furnish to the SEC.

Any forward-looking statements made herein speak only as of the date of this press release. Except as required by applicable law, we undertake no obligation to update any of these forward-looking statements for any reason after the date of this press release or to conform these statements to actual results or revised expectations.

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