atai Life Sciences Announces Completion of Phase 1 Study of VLS-01 in Healthy Participants

October 2, 2023

- *VLS-01, a proprietary oral transmucosal film (OTF) formulation of DMT, was well-tolerated with a favorable safety profile*
- *Pharmacokinetic and pharmacodynamic data confirmed systemic delivery of DMT via the oral, transmucosal route at levels comparable to those achieved with IV administration*
- *Company plans to further optimize VLS-01 in preparation for a Phase 2 study in treatment-resistant depression (TRD)*

NEW YORK and BERLIN, Oct. 02, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, announced the completion of the Phase 1 study of VLS-01 in healthy participants.

"We are pleased to report the completion of the Phase 1 study of VLS-01, in which we demonstrated a supportive PK/PD profile of our proprietary OTF formulation of DMT," said Florian Brand, CEO and Co-Founder of atai. "We plan to test a further optimized version of our OTF formulation in a forthcoming Phase 1b prior to initiating a Phase 2 study in TRD."

The Phase 1 study was designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of VLS-01 applied to the sublingual and buccal surfaces compared to intravenous (IV) DMT. The study enrolled a total of 74 healthy participants across three parts. The third part of the study evaluated VLS-01 administered and dosed as follows: sublingual 80mg (n=8), buccal 80mg with backing layer (n=10), and buccal 160mg with backing layer (n=8).

VLS-01 was well-tolerated with a favorable safety profile, and dose-dependent increases in exposure were observed. VLS-01 administration also resulted in subjective effects in most participants across doses. The company observed that participants that received 160mg of VLS-01 with a backing layer via buccal administration experienced the most robust and consistent increases in exposure and subjective effects compared to the other OTF cohorts, with results comparable to those seen in the IV cohort of DMT.

The company now plans to progress VLS-01 into a Phase 1b study in healthy participants. The study is expected to explore doses up to 160 mg with an optimized OTF formulation that incorporates taste masking, an intrinsic backing layer, and enhancements designed to increase permeability, with goals of further improving the participant experience and pharmacokinetics. The company has submitted a protocol to regulatory authorities and expects to enroll the first participant in a Phase 1b study in 1H 2024.

About VLS-01

VLS-01 is a proprietary OTF formulation of N,N-dimethyltryptamine (DMT). Pharmacologically, DMT is a partial agonist of the 5-HT 1A/2A/2C receptors, characterized by an intrinsically short duration of psychedelic effect, with a serum half-life estimated at less than 10 minutes. Clinical evidence suggests IV DMT administration results in rapid-acting antidepressant effects in patients with major depressive disorder (MDD). The company's proprietary OTF formulation is designed to eliminate the need for parenteral administration, provide improved PK compared to such routes of administration, and result in a psychedelic effect that resolves by approximately 45 minutes post dosing, thus allowing for—and maximizing 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, cost, and timing of development of VLS-01 (DMT) and related 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: our limited operating history, historical losses, and anticipation that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, including the development and any commercialization of our product candidates; we have never generated revenue and may never be profitable; our product candidates contain controlled substances, the use of which may generate public controversy; 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 and impact to such trials based on factors 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 and failure to recruit and retain a sufficient number of therapists; the timing and outcome of regulatory review and/or approvals, which are necessary prior to commercialization; 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, including our loan agreement with Hercules Capital, Inc.; our aggregate tax burden based on our management 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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