



atai Life Sciences Announces First Patient Dosed in Elumina, the Phase 2 Clinical Trial of VLS-01 for Treatment-Resistant Depression

March 11, 2025

- *Elumina is a Phase 2, multicenter, double-blind, randomized, placebo-controlled, clinical trial to assess the efficacy, safety and tolerability of VLS-01 (buccal film DMT) in people suffering from treatment-resistant depression*
- *VLS-01 is being developed as a rapid-acting, robust and durable antidepressant for people suffering from treatment-resistant depression, which affects approximately 100 million people globally*
- *VLS-01 is designed to fit within the established two-hour interventional psychiatry treatment paradigm*
- *Topline results from the Phase 2 Elumina trial are anticipated in the first quarter of 2026*

NEW YORK and BERLIN, March 11, 2025 (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 patient has been dosed in the Phase 2 Elumina trial of VLS-01, atai’s proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT) applied to the buccal surface, in people suffering from treatment-resistant depression (TRD).

"Dosing the first patient in the Phase 2 Elumina trial of VLS-01 marks a significant milestone in our commitment to transforming the treatment landscape for mental health disorders," stated Kevin Craig, M.D., Chief Medical Officer of atai. "Millions worldwide struggle with treatment-resistant depression, often left with few or no viable options. With VLS-01, we see the potential to offer rapid, robust, and durable antidepressant effects that could provide meaningful relief where existing treatments fall short. This trial brings us one step closer to delivering a new and innovative solution to those people who need it most."

Elumina is a Phase 2, multi-center, double-blind, randomized, placebo-controlled, clinical trial to assess the efficacy, safety and tolerability of repeated doses of VLS-01 ([NCT06524830](#)). The trial consists of two treatment periods. In the first treatment period, approximately 142 patients will be randomized 1:1 to receive a 120mg dose of VLS-01 or placebo on Day 1, followed by a second dose of the same intervention at Week 2. The primary endpoint is the change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 4. The last double-blind assessment visit will be at Week 14. The first treatment period will provide 12 weeks of blinded durability data following two doses of VLS-01 administered in a placebo-controlled fashion. Topline results from the first treatment period are anticipated in the first quarter of 2026.

The second treatment period starts at Week 14 and will explore the response to two different dose levels of VLS-01. Patients will be randomized 1:1 to receive a third dose of either 60mg or 120mg of VLS-01. Final safety and efficacy assessment will be conducted two weeks after administration of the third dose.

About VLS-01 (buccal film DMT)

VLS-01 is a proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT) applied to the buccal surface, being developed for the treatment of people suffering from treatment-resistant depression (TRD). Pharmacologically, VLS-01 is a partial to full agonist of the 5-HT_{1/2/6/7} receptors and is being developed to potentially offer rapid, robust, and durable efficacy with a favorable safety profile. VLS-01 is designed to fit within the established two-hour interventional psychiatry treatment paradigm, positioning it for integration into existing care models. atai is enrolling patients into Elumina, the Phase 2, multi-center, double-blind, randomized, placebo-controlled, trial to assess the efficacy, safety and tolerability of VLS-01 in people suffering from TRD. Topline results from the first treatment period of the Phase 2 Elumina trial are anticipated in the first quarter of 2026.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. The Company was founded in response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to developing novel, evidence-based therapeutics to treat depression, anxiety and other mental health disorders. 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. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, 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. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements relating to our business strategy and plans; and the potential, success, cost and timing of development of VLS-01 and related trials and studies.

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 factors described in the section titled “Risk Factors” in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 28, 2024, as such factors may be updated from time to time in atai’s other filings with the SEC. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

Contact Information

Investor Contact:

IR@atai.life

Media Contact:

PR@atai.life