



atai Life Sciences Announces Completion of Enrollment in Phase 2b Clinical Trial Evaluating BPL-003 for Treatment-Resistant Depression

March 5, 2025

- *The eight-week, quadruple-masked, dose-finding, core stage of the Phase 2b clinical trial is evaluating the efficacy and safety of a single dose of BPL-003 (mebufotenin benzoate) in patients with treatment-resistant depression*
- *The open-label extension stage of the Phase 2b clinical trial continues to enroll patients to evaluate the safety and efficacy of a second dose of BPL-003*
- *As previously reported, the Phase 2a study of BPL-003 in patients with treatment-resistant depression showed rapid and lasting antidepressant effects from a single dose, and patients were deemed ready for discharge within an average time of less than two hours after dosing*
- *Topline results from the core stage of the Phase 2b clinical trial are expected in mid-2025*

NEW YORK and BERLIN, March 05, 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 the completion of patient enrollment in the eight-week, double-blind, core stage of the global Phase 2b clinical trial evaluating BPL-003 (mebufotenin benzoate) in patients with treatment-resistant depression (TRD). BPL-003 is Beckley Psytech's patent-protected, proprietary intranasal formulation of mebufotenin benzoate, administered via a nasal spray device used in a previously approved drug product. BPL-003 is designed to deliver rapid and durable effects from a single dose, with a short time in clinic. Topline results from the core stage of the Phase 2b clinical trial are expected in mid-2025.

"We are impressed by the Beckley Psytech team's execution of the Phase 2b clinical trial of BPL-003 in patients with treatment-resistant depression, which is the largest controlled trial of mebufotenin and the first and only Phase 2b clinical trial to investigate mebufotenin in the U.S.," stated Srinivas Rao, M.D., Ph.D., Chief Executive Officer and Co-founder of atai. "The promising data from earlier clinical studies of BPL-003 have demonstrated that a single dose can induce rapid, significant, and lasting antidepressant effects, further reinforcing our confidence in its potential to revolutionize treatment for difficult-to-treat depression. We look forward to the topline results from the eight-week core stage of the Phase 2b clinical trial of BPL-003, which remains on track for mid-2025."

The eight-week, quadruple-masked, dose-finding, core stage of the Phase 2b clinical trial ([NCT05870540](#)) is evaluating the efficacy and safety of a single medium (8mg) or high (12mg) dose of BPL-003 against a sub-perceptual dose. The trial enrolled 196 patients with moderate-to-severe depression that had failed to respond to at least two or more prior treatments in the current episode of depression across 38 sites in six countries. Patients are followed for eight weeks, and efficacy is assessed at various timepoints by centralized, blinded raters using the Montgomery-Asberg Depression Rating Scale (MADRS).

The eight-week, open-label, extension stage of the Phase 2b clinical trial continues to enroll patients to evaluate the safety and efficacy of a second high dose of BPL-003 administered after the completion of the core stage of the trial.

Data from the Phase 2b clinical trial will be used in conjunction with data from the Phase 2a study of BPL-003 in patients with TRD to support end-of-Phase 2 meetings with regulatory bodies and Phase 3 planning in the second half of 2025. Initial Phase 2a data showed that a single 10mg dose of BPL-003 can produce a rapid and lasting antidepressant effect, with 55% of patients meeting the criteria for remission (MADRS ≤ 10) at Day 29 and 45% meeting the criteria for remission at Day 85. BPL-003 only required a short time in clinic, with patients deemed dischargeable within an average time of less than two hours after dosing.

About BPL-003

BPL-003 is Beckley Psytech's patent-protected, proprietary intranasal formulation of mebufotenin benzoate, administered via a nasal spray device used in a previously approved drug product. BPL-003 is designed to deliver rapid and durable effects from a single dose, with a short time in clinic. BPL-003 is being investigated for treatment-resistant depression (TRD) and for alcohol use disorder (AUD). In a Phase 2a study in patients with TRD, a single 10mg dose of BPL-003 produced a rapid antidepressant response in 55% of patients at Day 1, with 55% of patients in remission at Day 29 and 45% in remission at Day 85. BPL-003 demonstrated a short treatment duration, with patients deemed ready to be discharged within an average of less than two hours after dosing. Topline results from the eight-week, randomized, core stage of the Phase 2b clinical trial in patients with TRD are expected in mid-2025.

About Beckley Psytech Ltd

Beckley Psytech Ltd. is a private clinical-stage biopharmaceutical company dedicated to improving the lives of people with neuropsychiatric disorders through the development of rapid-acting, short-duration psychedelic medicines. In January 2024, [atai made a strategic investment in Beckley Psytech](#), resulting in an approximate one third ownership stake and 1:1 warrant coverage at a 30% premium on the primary issuances. atai holds a time-limited right of first refusal on a future sale of the company and an indefinite right of first negotiation for BPL-003 and ELE-101. atai and Beckley Psytech also agreed to collaborate on digital therapeutics, commercial and market access activities in preparation for future potential commercialization.

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 our product candidates, and the product candidates of those companies we invest in, including the progress of preclinical and clinical trials and related milestones such as BPL-003 and related data readouts.

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.

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