



atai Life Sciences Announces Positive Topline Data from Part 2 of Beckley Psytech's Phase 2a Study of BPL-003 in Combination with SSRIs for Treatment-Resistant Depression

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- *Positive results show that a single dose of BPL-003, administered adjunctively to SSRIs, produced a rapid and durable antidepressant effect for up to three months after dosing*
- *BPL-003 was well-tolerated and patients were able to be discharged within an average time of less than two hours after dosing*
- *Data from the eight-week core, randomized stage of Beckley Psytech's Phase 2b study of BPL-003 for treatment-resistant depression is expected in mid-2025*

NEW YORK and BERLIN, May 20, 2025 (GLOBE NEWSWIRE) -- [atai Life Sciences](#) (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes, today announced positive topline data from Part 2 of Beckley Psytech's Phase 2a study ([NCT05660642](#)) of BPL-003 (mebufotenin benzoate), for treatment-resistant depression (TRD). The findings show that a single dose of BPL-003, when given to patients who were also taking defined selective serotonin reuptake inhibitors (SSRIs), was well-tolerated, with rapid and durable antidepressive effects of up to three months with an average in-clinic treatment time of less than two hours following dosing.

"We're very encouraged by the growing body of data supporting BPL-003 as a potentially differentiated and commercially scalable interventional psychiatric treatment for depression," stated Srinivas Rao, M.D., Ph.D., Chief Executive Officer and Co-founder of atai. "Patients with treatment-resistant depression face limited options and these results show that a single dose of BPL-003 can deliver rapid and durable antidepressant effects when co-administered with an SSRI, extending the positive results observed in the Part 1 monotherapy study. Although a small, open-label study, the data validates the co-administration approach, which could improve accessibility in the real-world setting. Congratulations to Cosmo, Rob and the Beckley team for continued execution of the BPL-003 program, and we look forward to the Phase 2b readout mid-year."

The open-label Phase 2a study investigated the safety, efficacy and pharmacokinetics of a single dose of BPL-003 in 12 patients with moderate-to-severe depression, who had failed to respond to at least two or more prior treatments and were taking defined SSRIs. Patients were followed for 12 weeks post-dosing with assessments conducted at multiple points throughout the study.

BPL-003 was also shown to be well-tolerated. All adverse events were mild or moderate in severity and there were no serious adverse events reported (SAEs). Furthermore, acute effects resolved on the day of dosing with patients deemed dischargeable within an average time of less than two hours after dosing.

A single dose of BPL-003 induced rapid and long-lasting antidepressant effects, with a mean MADRS (Montgomery-Asberg Depression Rating Scale) reduction of 18 points from baseline observed the day after dosing, a mean MADRS reduction of 19 points from baseline observed one month after dosing, and a mean MADRS reduction of 18 points from baseline observed three months after dosing.

These findings demonstrate the potential of BPL-003 to deliver a commercially scalable single dose treatment model, if approved, that fits within the current interventional psychiatric care model established by Spravato®.

The results are also consistent with initial results from Part 1 of the study, which investigated BPL-003 as a monotherapy. Data from that study showed that a single dose of BPL-003 was well-tolerated and produced a rapid and lasting antidepressant effect for up to three months after dosing.

Beckley Psytech is expecting results from the core, randomized, quadruple-masked stage of its Phase 2b study of BPL-003 for TRD in mid-2025. The study enrolled 196 patients, which is the largest ever controlled clinical study to investigate mebufotenin and the only blinded Phase 2b study of mebufotenin in the United States. Data from the study will be used to support end-of-Phase 2 meetings with regulatory bodies and Phase 3 planning.

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 antidepressant effects from a single dose, with a short time in the clinic and is being investigated as a potential therapy for treatment resistant depression (TRD) and for alcohol use disorder (AUD). BPL-003 is covered by granted US, UK and European composition-

of-matter patents, with multiple further claims pending in various jurisdictions.

About Treatment-Resistant Depression

Depression is a debilitating and life-changing condition affecting nearly 300 million people across the globe, with around 52 million people affected by the condition in Europe and the US combined. Treatment resistant depression occurs when an individual does not respond to two or more courses of antidepressants and some studies show that it may affect up to 50% of those living with depression, meaning there is a significant unmet need for more effective treatments.

About Beckley Psytech

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 on a mission to develop highly effective mental health treatments to transform patient outcomes. Our pipeline of psychedelic-based therapies includes VLS-01 (buccal film DMT) for treatment-resistant depression (TRD) and EMP-01 (oral R-MDMA) for social anxiety disorder, which are in Phase 2 clinical development. We are also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD. These programs aim to address the complex nature of mental health providing commercially scalable interventional psychiatry therapies that can integrate seamlessly into healthcare systems. For the latest updates and to learn more about our mission, visit www.atai.com or follow us on [LinkedIn](#).

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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "anticipate," "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: our business strategy and plans; 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 important 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"), 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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