atai Life Sciences Announces Dosing of First Patient in Part 2 of Beckley Psytech's Phase 2a Study Exploring BPL-003 Adjunctive to SSRIs in Patients with Treatment Resistant Depression

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- *The BPL-003 Phase 2a trial is an open-label study investigating BPL-003 as both monotherapy and adjunctive to SSRIs in patients with Treatment Resistant Depression.*
- *Initial results from the recently completed monotherapy Part 1 of the study were shared in March 2024, and showed that a single dose of BPL-003 was safe and well-tolerated, with a rapid and durable antidepressant effect lasting up to 12-weeks post-dose.*
- *Part 2 of the study will investigate a single dose of BPL-003 in patients who are currently on a course of SSRI antidepressants.*
- *The first patient has been dosed in Part 2 of the study and initial results are expected in H1 2025.*

NEW YORK and BERLIN, April 24, 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 patient has been dosed in Part 2 of Beckley Psytech's Phase 2a study, evaluating BPL-003 (intranasal 5-MeO-DMT) in patients living with Treatment Resistant Depression (TRD).

In Part 2 of this open-label Phase 2a study (NCT05660642), patients with moderate-to-severe TRD who are on a stable course of certain oral selective serotonin reuptake inhibitor (SSRI) antidepressants will receive a single dose of BPL-003 alongside psychological support to explore the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of BPL-003 as an adjunctive therapy to SSRIs. Patients will be followed for 12 weeks post-dosing. Initial results are expected in H1 2025.

Commenting on Part 2 of the trial, Florian Brand, CEO and Co-Founder of atai, said: *"Many clinical trials investigating psychedelics require patients to discontinue their existing antidepressant medication. The findings from this adjunctive therapy part of the BPL-003 Phase 2a study will help to inform whether BPL-003 could be a safe and effective therapy in combination with SSRIs, which could allow for broader patient access, should BPL-003 reach approval."*

Part 1 of the Phase 2a study investigating BPL-003 for TRD assessed a single 10mg dose of BPL-003 alongside psychological support in patients with moderate-to-severe TRD who were not taking concomitant antidepressants. Initial data showed that a single dose of BPL-003 induced a rapid antidepressant response[1] in 55% of patients on the day after dosing. The antidepressant effect was durable, with a 55% response rate maintained at week 4, which continued to week 12. There were 55% of patients in remission[2] at week 4 and 45% in remission at week 12. BPL-003 was also shown to require a short time in clinic with acute effects resolving on average in less than two hours, highlighting the potential of BPL-003 to deliver a scalable single dose treatment model that could fit within the existing Spravato® two-hour treatment paradigm.

The BPL-003 Phase 2b study is currently underway, evaluating the effects of a single medium or high dose of BPL-003 against a sub-perceptual dose in TRD patients (NCT05870540). Initial results from that study are expected in H2 2024.

References

[1] *Response rate defined as ≥50% reduction in MADRS score.*

[2] *Remission rate defined as MADRS score ≤10.*

About Beckley Psytech and BPL-003

Beckley Psytech is a private clinical-stage biopharmaceutical company developing BPL-003, which is a novel, patent-protected, synthetic benzoate salt formulation of 5-MeO-DMT which is delivered intranasally. It is a short-duration psychedelic compound that binds to a variety of serotonergic receptors. Epidemiological surveys and observational studies have reported that 5-MeO-DMT is associated with improvements in mood, anxiety, reduced stress, increased life satisfaction and mindfulness. 5-MeO-DMT has been reported to produce mystical experiences with comparative intensity as seen with high doses of psilocybin but has a significantly shorter duration of effect.

In January 2024, atai made a strategic investment in Beckley Psytech, resulting in a 35.5% 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 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 BPL-003 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, 2023, filed with the Securities and Exchange Commission ("SEC"), 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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