atai Life Sciences Announces the Publication of Beckley Psytech's Phase 1 Study of BPL-003 in the Journal of Psychopharmacology

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- *BPL-003 is Beckley Psytech's novel patent-protected benzoate salt formulation of 5-MeO-DMT that is administered intranasally.*
- *BPL-003 was shown to be safe and well-tolerated with a predictable pharmacokinetic profile and a reliable induction of subjective psychedelic effects with single doses of up to 12 mg in healthy participants.*
- *Subjective psychedelic effects correlated with 5-MeO-DMT exposure and had a rapid onset and short duration, with acute effects resolving in less than two hours.*

NEW YORK and BERLIN, April 17, 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 the publication of the Phase 1 results of BPL-003, Beckley Psytech's novel, synthetic, intranasal benzoate salt formulation of 5-MeO-DMT, in *The Journal of Psychopharmacology.*

The double-blind, placebo-controlled, single ascending dose Phase 1 study explored the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of BPL-003 in combination with psychological support in 44 psychedelic-naïve healthy volunteers. Participants across seven cohorts were given either a single dose of BPL-003 between 1 mg to 12 mg or a placebo.

The paper shows that BPL-003 was safe and well-tolerated with no serious or severe adverse events reported. BPL-003 was rapidly absorbed and eliminated, with 5-MeO-DMT systemic exposure increasing approximately dose-proportionally. There was a reliable onset of subjective psychedelic effects within minutes, which resolved in less than two hours. If confirmed in larger studies, these findings could support a scalable single dose treatment model fitting within the existing interventional treatment paradigm.

The intensity of the subjective psychedelic experience was shown to correlate with exposure to the compound. The PD endpoint scores of the Mystical Experience Questionnaire (MEQ-30) and Ego Dissolution Inventory (EDI) increased with an increase in the BPL-003 dose. Sixty percent of participants had a 'complete mystical experience,' which is defined as reaching or exceeding a score of three on all four subdomains of the MEQ-30 scale, at 10 mg and 12 mg doses of BPL-003. Notably, 87% of participants who received BPL-003 said they would accept the same or higher dose again, with 100% of participants who received the highest (12 mg) dose stating they would accept the same or higher dose again.

Commenting on the publication, Florian Brand, CEO and Co-Founder of atai, said: *"We are pleased by the publication of the BPL-003 Phase 1 data in the Journal of Psychopharmacology, a well-regarded, peer-reviewed journal. Consistent with the initial Phase 2a data reported recently, the Phase 1 results showed that BPL-003 was safe and well-tolerated and underscore its potential as a scalable interventional treatment requiring two hours or less in the clinic, in line with the treatment paradigm successfully established by Spravato®."*

BPL-003 is currently under investigation in Phase 2a studies as a potential treatment for Alcohol Use Disorder (NCT05674929) and Treatment Resistant Depression (TRD) (NCT05660642). It is also being explored in a multi-site Phase 2b study (NCT05870540) for TRD. The trial is evaluating the effects of a single, medium, or high dose of BPL-003 against a sub-perceptual dose in TRD patients not taking concomitant antidepressants. Initial results from that study are expected in H2 2024.

About Beckley Psytech and BPL-003

Beckley Psytech is a private clinical-stage biopharmaceutical company developing BPL-003, which is 5-MeO-DMT, a short-duration psychedelic tryptamine 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.

Contact Information

Investor Contact:

IR@atai.life

Media Contact:

PR@atai.life