atai Life Sciences Announces Positive Initial Results from Beckley Psytech's Phase 2a Open Label Study of BPL-003 (Intranasal 5-MeO-DMT) in Treatment Resistant Depression

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- A single dose of BPL-003 demonstrated a rapid and durable antidepressant effect in TRD patients, with 45% of patients in clinical remission at week 12

- 55% of patients achieved a clinical response on the day after dosing and this rate of response was maintained at week 4 and week 12

- BPL-003 showed a good safety profile and was well-tolerated with no serious adverse events reported

- Acute effects resolved on average in less than two hours, highlighting BPL-003's potential to fit within the Spravato ® two hour in-clinic treatment paradigm

- Phase 2b study of BPL-003 in 225 TRD patients is underway with top-line results expected in H2 2024

NEW YORK and BERLIN, March 27, 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 positive initial results from Beckley Psytech's Phase 2a open label study of BPL-003 in Treatment Resistant Depression (TRD), a condition that affects approximately 100 million people worldwide.

BPL-003 is a novel, synthetic, patent-protected benzoate salt formulation of 5-MeO-DMT (mebufotenin) administered intranasally. Initial results demonstrated that a single 10mg dose of BPL-003 was well-tolerated and resulted in a rapid onset and durable antidepressant effect in patients living with TRD.

The open-label Phase 2a study investigated the safety, tolerability and efficacy of a single 10mg dose of BPL-003 alongside psychological support in patients with moderate-to-severe TRD who were not taking concomitant antidepressants. 12 subjects were dosed, and 11 met the criteria for per-protocol analysis[1]. Patients were followed for 12 weeks post-dosing, with assessments conducted at multiple points throughout the study. Efficacy was assessed using the Montgomery–Åsberg Depression Rating Scale (MADRS).

Initial analysis showed that a single dose of BPL-003 induced a rapid antidepressant response[2] 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[3] at week 4 and 45% in remission at week 12. These findings represent the longest known follow-up of depression outcomes in a clinical study of 5-MeO-DMT.

BPL-003 showed a good safety profile and was well tolerated. Adverse events (AEs) were predominantly mild or moderate and the most common AEs (>10%) were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings. No serious AEs were reported.

Acute effects resolved on average in less than two hours. These data suggest that BPL-003 could offer a shorter in-clinic treatment time when compared to other psychedelic treatments currently in development.

Commenting on the results, Florian Brand, Chief Executive Officer and Co-Founder of atai Life Sciences said: "We are thrilled with the progress the Beckley Psytech team has made on the BPL-003 program. The positive data from the Phase 2a study is highly encouraging as we await the results of the larger Phase 2b study anticipated later this year. With around half of TRD patients in remission three months after just a single dose of BPL-003 in this study, we are particularly excited about its antidepressant durability potential. The results indicate that BPL-003 could offer a scalable, single-dose administration within the two hour in-clinic treatment paradigm successfully established by Spravato®."

A Part 2 extension of this Phase 2a open label study is now enrolling patients with TRD who are on stable doses of oral antidepressants to assess the safety and efficacy of BPL-003 co-administration (NCT05660642).

A randomized, quadruple-masked, controlled Phase 2b study of BPL-003 is currently underway (NCT05870540). The study is investigating the effects of a single 12mg or 8mg dose of BPL-003 against a sub-perceptual dose of 0.3mg in 225 patients with

TRD. Efficacy will be assessed by masked raters using the MADRS scale at several time points with the primary endpoint at week 4 and final assessment at week 8. Top-line results are expected in H2 2024.

[1] Prior to data analysis, one subject (from total of 12 patients) was determined not to meet multiple per protocol eligibility criteria and was excluded from the efficacy analysis.

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

[3] 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 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. Phase 1 data showed BPL-003 to be well-tolerated with consistent dose delivery and a reproducible, dose-linear pharmacokinetic profile.

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, 2022, filed with the Securities and Exchange Commission (“SEC”) and our quarterly reports on Form 10-Q, 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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