atai Life Sciences Announces Positive Topline Results from Beckley Psytech's BPL-003 (intranasal 5-MeO-DMT benzoate) Phase 2a Open-Label Study for Alcohol Use Disorder

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- A single dose of BPL-003, combined with relapse prevention therapy, produced meaningful and sustained reductions in alcohol use, with 50% of patients maintaining complete abstinence out to three months

- BPL-003 was well-tolerated with no serious or severe adverse events reported

NEW YORK and BERLIN, Jan. 28, 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 positive topline results from Beckley Psytech's Phase 2a open-label study of BPL-003 in 12 patients with moderate to severe alcohol use disorder (AUD). BPL-003 is a patent-protected synthetic intranasal formulation of 5-MeO-DMT benzoate designed to deliver rapid and durable treatment effects from a single dose with a short in-clinic treatment time. The results showed that a single dose of BPL-003, in combination with relapse prevention cognitive behavioral therapy, induced meaningful and sustained reduction in alcohol use and heavy drinking days (HDDs) in patients with moderate to severe AUD out to 12 weeks.

"We are encouraged by these exploratory results from Beckley Psytech, our strategic investment, which demonstrate the potential of short in-clinic psychedelic therapies to transform the treatment of substance use disorders," stated Dr. Srinivas Rao, CEO and Co-founder of atai. "The high rates of sustained abstinence in this study are particularly promising given the significant challenges patients with alcohol use disorder face in achieving and maintaining abstinence. These findings add to the growing body of evidence supporting the potential of BPL-003 in treating serious mental health disorders. We look forward to the Phase 2b data readout of BPL-003 in treatment-resistant depression expected mid-year."

The 12-week Phase 2a open-label study enrolled 12 patients with moderate to severe AUD and evaluated the safety, tolerability, pharmacodynamic effects and impact on alcohol use of a single dose of BPL-003, in combination with relapse prevention cognitive behavioral therapy (NCT05674929). The results demonstrated meaningful and sustained reductions in alcohol use following a single dose of BPL-003:

- Mean number of alcohol units consumed per day decreased from 9.3 units to 2.2 units at Week 12
- Mean percentage of HDDs, defined as consuming seven or more units of alcohol per day for women and nine or more units of alcohol per day for men, declined from 56% to 13% at Week 12
- Mean number of abstinent days increased from 33% to 81% at Week 12
- 50% of the patients remained completely abstinent through the 12-week study

BPL-003 was shown to be well-tolerated with adverse events (AEs) being reported as mild or moderate and there were no serious or severe adverse events reported. Most patients were assessed as ready for discharge within approximately two hours.

Beckley Psytech plans to evaluate future development options for BPL-003 in substance use disorders and anticipates reporting additional clinical data from this study in publications and conferences in 2025.

About Alcohol Use Disorder (AUD)
AUD is a medical condition characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences. The World Health Organization estimates that around 400 million people suffer with AUD worldwide, with around 3 million deaths each year attributed to the harmful use of alcohol. Currently available pharmacological treatment options are not very effective and some people with alcohol use disorder who wish to abstain from, or reduce, alcohol consumption do not achieve their treatment goal with currently approved treatment options. This contributes to an unmet need for more effective medical treatments.

About BPL-003
BPL-003 is Beckley Psytech's patent-protected synthetic intranasal 5-MeO-DMT benzoate formulation, 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 TRD study, 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. Topline Phase 2b data are anticipated 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 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. 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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