atai Life Sciences Announces Update on Beckley Psytech's Phase 1/2a Trial of ELE-101 (IV Psilocin) for Major Depressive Disorder, with Initial Results from Phase 1 and First Patients Dosed in Phase 2a

June 20, 2024

- ELE-101 is a patent-protected, synthetic formulation of psilocin, designed to offer the therapeutic benefits of psilocybin in a more consistent, controllable, and shorter treatment paradigm of approximately two hours.
- The Phase 2a part of the study will evaluate the safety, tolerability, subjective effects, and efficacy of a single intravenous (IV) dose of ELE-101 in 6-12 participants with Major Depressive Disorder (MDD). Results are expected in H2 2024.
- The dose for Phase 2a was selected using preliminary pharmacokinetic (PK) and pharmacodynamic (PD) data from the Phase 1 randomized, double-blind, placebo-controlled, single ascending dose part of the study of ELE-101 in healthy participants, which showed that it was well-tolerated with no serious adverse events. ELE-101 showed a dose-proportional PK profile and a reliable induction of short-duration psychedelic experiences.

NEW YORK and BERLIN, June 20, 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 an update on Beckley Psytech's Phase 1/2a trial of ELE-101 (NCT05434156) for people living with MDD, with initial results from Phase 1 and the dosing of the first patients in the Phase 2a part of the study.

ELE-101, a patent-protected IV formulation of psilocin, has been designed to provide consistent and controllable drug delivery in patients with neuropsychiatric conditions. As the active metabolite of psilocybin, psilocin has the potential to offer a rapid onset, significantly shorter treatment duration, and reduced inter-subject variability compared to oral formulations of psilocybin. This could enhance convenience and therapeutic outcomes for patients with depression while reducing the resource burden on healthcare systems.

The open-label Phase 2a part of the study will evaluate the safety, tolerability, subjective effects, and efficacy of a single IV dose of ELE-101 in 6-12 patients diagnosed with MDD. Patients will be assessed at various time points in the study for up to three months after dosing, with results expected in H2 2024.

The dose was selected using preliminary PK/PD data from the Phase 1 part of the study, a randomized, double-blind, placebo-controlled, single ascending dose study of ELE-101 in healthy participants. Initial data from Phase 1 supports the differentiated profile of ELE-101, showing that ELE-101:

- Was well-tolerated with no serious or severe adverse events (AE) reported, and an AE profile which is consistent with other compounds in this class.
- Demonstrated a dose-proportional PK profile, leading to reduced inter-subject variability compared to oral psilocybin.
- Induced high-intensity, short-duration psychedelic experiences, suggesting a potential treatment time of approximately two hours in the clinic. If validated in further studies, these findings could support the development of a scalable treatment model similar to the established paradigm of Spravato®, an esketamine nasal spray for treatment-resistant depression.

Full data from the Phase 1 study is expected to be published at a later date.

Commenting on the news, Dr Srinivas Rao, Co-CEO of atai said: "The data so far on ELE-101 indicates its potential as a promising candidate for treating depression. The consistent dose delivery and dose-proportional pharmacokinetic profile are particularly encouraging, as this could reduce variability among patients. At atai we are building a pipeline of short-duration psychedelics that target in-clinic treatments of approximately two hours. In addition to ELE-101, we believe Beckley Psytech's lead candidate, BPL-003 (an intranasal 5-MeO-DMT), and our VLS-01 (an oral transmucosal formulation of DMT) could also fit this model."

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.

About Beckley Psytech

Beckley Psytech is a private clinical-stage biopharmaceutical company focused on 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.

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," "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: expectations regarding the progress of preclinical and clinical trials and related milestones, including for ELE-101, BPL-003 and VLS-01; expectations regarding our strategic investment in Beckley Psytech our business strategy and plans; and the plans and objectives of management for future operations and capital expenditures.

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.

Contact Information

Investor Contact:

IR@atai.life

Media Contact:

PR@atai.life