atai Life Sciences Announces First Patient Dosed in Phase 2 Study of EMP-01 for the Treatment of Social Anxiety Disorder

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- In a Phase 1 study, EMP-01 (oral R-MDMA) demonstrated a unique, dose-dependent subjective effect profile that was generally found to be more similar to classical psychedelics than to racemic MDMA

- The exploratory, randomized, double-blind, placebo-controlled Phase 2 study will assess the safety, tolerability and efficacy of EMP-01 in adults with social anxiety disorder

- Topline data anticipated in the first quarter of 2026

NEW YORK and BERLIN, May 13, 2025 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes, today announced that the first patient has been dosed in the exploratory Phase 2 study of EMP-01 (R-3,4-methylenedioxy-methamphetamine (R-MDMA)) for the treatment of social anxiety disorder (SAD).

"We are pleased to have dosed the first patient in the exploratory Phase 2 study evaluating EMP-01 in adults with social anxiety disorder," stated Kevin Craig, M.D., Chief Medical Officer of atai. "Social anxiety disorder affects millions and remains significantly underserved by current treatment options. We believe this Phase 2 study will provide critical insights into EMP-01's potential to address this large and growing market with substantial unmet need."

The Phase 2 study is an exploratory, randomized, double-blind, placebo-controlled trial (NCT06693609) to assess the safety, tolerability and efficacy of EMP-01 in approximately 60 adults with SAD. Patients will be randomized 1:1 to receive two double-blind administrations of either EMP-01 or placebo, spaced four weeks apart. Symptoms will be monitored for six weeks following the first dose. The primary objective of the study is to assess the safety and tolerability of EMP-01 in adults with SAD. The secondary objective is to estimate any improvements in social anxiety symptoms compared to placebo.

About EMP-01 (Oral R-MDMA)
EMP-01 is an oral formulation of R-3,4-methylenedioxy-methamphetamine (R-MDMA) that demonstrated a unique, dose-dependent subjective effect profile in a Phase 1 trial that was generally found to be more similar to classical psychedelics than to racemic MDMA. Anxiety disorders are the most common mental health disorders worldwide, affecting how one experiences worry, fear and anxiety in everyday situations. Social anxiety disorder (SAD) is an area of high unmet medical need with approximately 18 million people currently diagnosed in the United States and no novel molecules approved in over two decades. atai is currently enrolling patients into an exploratory, randomized, double-blind, placebo-controlled Phase 2 study to assess the safety, tolerability and efficacy of EMP-01 in adults with SAD. Topline data from the Phase 2 study is anticipated in the first quarter of 2026.

About atai Life Sciences
atai is a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes. Our pipeline of psychedelic-based therapies includes VLS-01 (buccal film DMT) for treatment-resistant depression (TRD) and EMP-01 (oral R-MDMA) for social anxiety disorder, which are in Phase 2 clinical development. We are also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD. These programs aim to address the complex nature of mental health providing commercially scalable interventional psychiatry therapies that can integrate seamlessly into healthcare systems. For the latest updates and to learn more about our mission, visit www.atai.com or follow us on LinkedIn.

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," "anticipate," "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: our business strategy and plans; the potential, success, cost and timing of development and progress of trials and related milestones of our product candidates such as EMP-01; expectations regarding our cash runway; and the plans and objectives of management for future operations, research and development 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.

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