# atai Life Sciences Announces Positive Topline Results from Single Ascending Dose Phase 1 Study with EMP-01 (R-MDMA)

January 2, 2024

- *EMP-01 (R-MDMA) was generally well-tolerated and treatment-related adverse events (AEs) were as expected*
- *The PK profile of EMP-01 was dose-proportional, and a range of exploratory pharmacodynamic (PD) measures, including subjective reports and blood-based biomarkers, showed dose-dependent changes*
- *EMP-01 administration resulted in a differentiated subjective experience compared to racemic MDMA, a result that is likely to have therapeutic implications*

NEW YORK and BERLIN, Jan. 02, 2024 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, announced positive results from its Phase 1 study evaluating orally administered EMP-01, the R-enantiomer of MDMA (3,4-methylenedioxy-methamphetamine).

The goals of this Phase 1 study were to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of EMP-01. The four-cohort, single-ascending dose, randomized, double-blind, placebo-controlled study enrolled 32 healthy participants who received 75mg, 125mg, 175mg or 225mg of EMP-01 or placebo in a 6+2 design.

EMP-01 was well-tolerated, and treatment-related adverse events (AEs) were all expected and generally dose dependent. There were no study discontinuations, and no serious or severe AEs were observed in the study. Non-clinically significant increases in blood pressure and heart rate were observed, though such changes showed limited dose dependency. Further, the peak body temperatures observed fell within the normal range. Finally, bruxism was observed in only 1 of 24 subjects that received EMP-01.

The PK profile of EMP-01 was dose-proportional. The PD measures included both subjective reports and blood-based biomarkers. Significant, consistent and dose-dependent changes were seen on several of these exploratory PD measures. EMP-01 administration resulted in a differentiated subjective experience compared to racemic MDMA on standard psychedelic experience questionnaires. Further, dose dependent changes on measures of emotional breakthrough, a phenomenon thought to be a key mediator of the long-term psychological changes associated with psychedelics, were noted in this healthy volunteer population.

Detailed clinical data from the Phase 1 study of EMP-01 are expected to be presented at a future medical meeting.

"I am grateful to the participants and investigators, as well as the members of the atai study team on the successful completion of this Phase 1 study," said Florian Brand, CEO and Co-Founder of atai. "Building upon the decades of research into MDMA as a potential treatment for mental health disorders, including two positive Phase 3 studies in PTSD, we are encouraged by the unique characteristics of EMP-01 and exploring the implications for further clinical development."

"The two enantiomers of MDMA show markedly different and rich pharmacology. The present study is one of the first specifically focused on assessing the PK and PD of R-MDMA," said Srinivas Rao, CSO of atai. "We found differences in the subjective experience of R-MDMA in comparison to published reports involving racemic MDMA. If confirmed, these differences suggest that R-MDMA may have applicability in a broad array of mental health conditions."

**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 EMP-01 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: our limited operating history, historical losses, and anticipation

that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, including the development and any commercialization of our product candidates; we have never generated revenue and may never be profitable; our product candidates contain controlled substances, the use of which may generate public controversy; 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 and impact to such trials based on factors 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 and failure to recruit and retain a sufficient number of therapists; the timing and outcome of regulatory review and/or approvals, which are necessary prior to commercialization; 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, including our loan agreement with Hercules Capital, Inc.; our aggregate tax burden based on our management 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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