atai Life Sciences Announces Initiation of Phase 1 Trial for its MDMA Derivative, EMP-01

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- atai's wholly owned subsidiary, EmpathBio, has received Medsafe central regulatory and The Health and Disability Ethics Committees (HDEC) ethics approvals to initiate a Phase 1 trial to assess the safety and tolerability of orally administered EMP-01 in 32 healthy volunteers

- EMP-01 is a 3,4-methylenedioxy-methamphetamine (MDMA) derivative under development for the treatment of post-traumatic stress disorder (PTSD) and other indications

NEW YORK and BERLIN, Sept. 27, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) ("atai"), which is developing EMP-01, a 3,4-methylenedioxy-methamphetamine (MDMA) derivative for the treatment of post-traumatic stress disorder (PTSD) and other indications, announced today its Phase 1 study has received regulatory and ethics approvals required from Medsafe and HDEC, respectively, to initiate participant enrollment.

The Phase 1 randomized, double-blind, placebo-controlled study is designed to evaluate the safety and tolerability of single-ascending doses of EMP-01 in healthy adult participants, as well as assess the usability and acceptability of the IDEA-1 app in delivering "set and setting" content to participants in preparation for their EMP-01 administration. This study also includes a range of behavioral assessments that, in conjunction with the PK and safety readouts, are expected to inform the design of and doses tested in future Phase 2 clinical trials of EMP-01.

In the U.S. alone, an estimated 9.3 million people meet the criteria for a PTSD diagnosis according to the National Institute of Health. At present, the only FDA-approved treatments for PTSD are two selective serotonin reuptake inhibitors (SSRIs), paroxetine and sertraline. Evidence shows that two-thirds of patients either do not respond or have only a partial response to these medications.

MDMA itself is an amphetamine derivative that possesses complex pharmacology and is believed to act by increasing the release of monoamines like serotonin, norepinephrine, and dopamine in the brain, as well as stimulating neurohormonal activity. Studies show that this activity may result in the anxiolytic, prosocial, and empathic responses commonly associated with the approximately six-hour experience. As a result, MDMA is often classified as an entactogen rather than a typical psychedelic.

EmpathBio is focused on developing MDMA derivatives with different pharmacological profiles than MDMA. These modifications are designed to separate the entactogenic effects of MDMA from some of the known side effects, specifically its stimulant-associated effects. This may result in an improved safety profile compared to MDMA in the treatment of PTSD populations with comorbidities including hypertension, history of stroke, and cardiovascular disease. If successful, such an approach could help minimize some of the transient physiological changes caused by MDMA and potentially expand the PTSD patient pool medically eligible for the therapy.

"The need for new interventions for PTSD is critical given the current lack of effective treatments for those suffering from this debilitating mental health disorder," said Florian Brand, CEO of atai Life Sciences. "We are thrilled to have received the necessary approvals for the initiation of the Phase 1 trial for EMP-01 in order to further progress the potential development of this promising new therapy."

"Data on MDMA-assisted psychotherapy strongly suggests its potential for the treatment of PTSD," said Glenn Short, Senior Vice President, Early Development of atai Life Sciences. "However, we are focused on refining MDMA's entactogenic pharmacology to provide a greater therapeutic index. This study is a critical step towards ensuring that entactogen-assisted therapy is available to everyone who is struggling with PTSD."

atai anticipates topline results in H2 2023 for this Phase 1 study.

About atai Life Sciences
atai Life Sciences is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. Founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape, atai is dedicated to acquiring, incubating, and 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 across its companies 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 EmpathBio
EmpathBio is a biotech company dedicated to developing 3,4-methylenedioxymethamphetamine derivatives in conjunction with digital therapeutics to deliver efficient, scalable treatments to patients on their own terms.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, 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. Forward-looking statements include express or implied statements relating to, among other things: statements regarding the trials by EmpathBio and future activities thereunder, the potential of EMP-01, the success, cost and timing of development of our product candidates, including the progress of preclinical and clinical trials and related milestones; our business strategy and plans; potential acquisitions; and the plans and objectives of management for future operations and capital expenditures. The forward-looking statements in this press release are neither promises

nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance, or achievements to differ materially from those expressed or implied by these forward-looking statements.

The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, including without limitation: we are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts; our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability; we have never generated revenue and may never be profitable; clinical and preclinical development is uncertain, and our preclinical programs may experience delays or may never advance to clinical trials; we rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts; and a pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results. These and other important factors described in the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission (“SEC”), our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as updated by our subsequent filings with the SEC, may cause our actual results, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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