atai Life Sciences Announces Initiation of Phase 1 Proof-of-Concept Clinical Trial for Its Sol-gel Based Direct-to-Brain Drug Delivery Technology

October 18, 2022

– atai has initiated a Phase 1 proof-of-concept clinical trial to demonstrate the safety, tolerability, and direct-to-brain delivery of intranasal INB-01, a sol-gel based drug-delivery technology.

– INB-01 may enable direct-to-brain delivery of various compounds in development across atai's pipeline, with topline results expected in H1 2023.

– Potential advantages may include ease of administration, increased patient compliance, lower dose requirements, rapid onset of action, and minimized systemic exposure.

NEW YORK and BERLIN, Oct. 18, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences ("atai" or the "Company") (NASDAQ: ATAI), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders today announced the initiation of the Phase 1 proof-of-concept (PoC) clinical trial of intranasal INB-01, a sol-gel based, excipient (drug-delivery) technology.

This is a Phase 1 two-stage, open-label, randomized study of the safety, tolerability, and effective brain delivery of INB-01. INB-01 or placebo will be administered to subjects using the Aptar Nasal Drug Delivery Device. Topline results are expected in H1 2023.

Traditional oral or intravenous drug delivery methods can be problematic in the treatment of central nervous system (CNS) disorders. When drugs are delivered via these peripheral methods, the blood–brain barrier restricts the entry of therapeutic agents to the CNS, thereby decreasing drug efficacy.

A potential solution is direct-to-brain delivery through the nose. This method has the potential to be a non-invasive administration route and may offer additional advantages such as ease of administration, increased patient compliance, lower dose requirements, rapid onset of action, and minimized systemic exposure, which may reduce the risk of peripheral toxicity.

Our INB-01 technology is designed to deliver pharmaceutical compounds as a liquid at room temperature, which becomes a gel instantaneously in the nasal cavity. The novel technology has been successfully utilized with both water-soluble and insoluble compounds and extracts. Prior to launching this PoC trial in humans, dosing of INB-01 has shown positive results in animals when measuring levels of INB-01 in the brain as well as MRI imaging of the brain. These results are a promising predictor for the use of INB-01 in human subjects for intranasal direct-to-brain drug delivery.

"Exploring the mechanism of drug delivery is an opportunity for us to further enhance the treatment experience," said Florian Brand, Co-Founder, and CEO of atai Life Sciences. "INB-01 has the potential to provide superior drug uptake via the nose-brain barrier, reducing dose administered and dosing frequency. We are confident this will help patients and healthcare practitioners by easing administration, dosing, and providing faster relief to improve compliance."

Dr. Majed Fawaz, Vice President, Chemistry, Manufacturing & Controls at atai, further commented, "INB-01 offers a novel direct-to-brain delivery technology that will support the lifecycle of atai's drug development pipeline. We are thrilled to commence the Phase 1 proof-of-concept trial for INB-01. This is the first important step in understanding the safety, tolerability, and brain delivery potential of INB-01 in healthy adult subjects prior to pairing it with active pharmaceutical ingredients."

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

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 InnarisBio and future activities thereunder, the potential of INB-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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