atai Life Sciences Announces Successful Outcome of Phase 2a Biomarker Trial of RL-007 in Cognitive Impairment Associated with Schizophrenia

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RL-007 was well tolerated and demonstrated a clinically meaningful pro-cognitive profile

Changes in quantitative electroencephalogram (qEEG) were consistent with the results of a previous Phase 1 trial of RL-007

These results support the progression of RL-007 to a double-blind, placebo-controlled Phase 2 trial focused on cognition

NEW YORK, Dec. 14, 2021 (GLOBE NEWSWIRE) -- atai Life Sciences (Nasdaq: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced positive topline data from its Phase 2a study of RL-007 for Cognitive Impairment Associated with Schizophrenia (CIAS).

The 32-patient, single-arm, single-blind study demonstrated a clinically meaningful pro-cognitive profile for RL-007, based on analysis of general cognition and episodic memory. Additionally, the trial showed changes in quantitative electroencephalogram (qEEG) that are consistent with previous results of a prior study of healthy volunteers. Together, the results support atai's decision to progress RL-007 to a double-blind, placebo-controlled Phase 2 trial focused on cognition.

The topline Phase 2a data showed dose-related improvements on exploratory cognitive endpoints. These included the Brief Assessment of Cognition in Schizophrenia, Symbol Coding Test (Symbol Coding) and Hopkins Verbal Learning Task (HVLT), focusing on general cognitive function and episodic memory, respectively.[1,2] The dose-responsive improvement of Symbol Coding and HVLT replicated the previously observed cognitive bi-phasic dose response of RL-007. Importantly, Symbol Coding is a highly sensitive cognitive endpoint in CIAS patients, has a high correlation with patient outcome, and is a key component of the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) Consensus Cognitive Battery (MCCB™).[3]

In addition to the pro-cognitive effects, a dose dependent response in qEEG was observed, with the greatest increases seen in 20mg and 40mg doses of RL-007. The qEEG data demonstrated salient increases in amplitude in the alpha band (up to 17% increase in normalized, baseline adjusted band power) and in the alpha-slow wave index (up to 21% increase), both markers of alertness believed to correlate with aspects of cognition.[4]

Notably, these findings recapitulate promising results from a previous study of RL-007 in a human model of cognitive impairment utilizing a scopolamine challenge. This previous trial observed similar qEEG responses and changes in a word recall task within the same dose range. Recognify Life Sciences, an atai Life Sciences platform company, is conducting the current and upcoming RL-007 trials in CIAS.

"The impact of cognitive impairment in schizophrenia can be debilitating and limit the ability of patients to conduct everyday tasks. These Phase 2a results further reinforce our belief in RL-007 to provide benefit in this challenging condition," said Florian Brand, CEO and Co-Founder of atai Life Sciences.

"These exciting Phase 2a results extend previously observed clinical activities of RL-007 to CIAS patients and support advancement to the next clinical trial, which will be designed to assess cognitive benefits in a double-blind, placebo-controlled manner," said Matthew Pando, PhD, CEO and Co-Founder of Recognify Life Sciences. "These results demonstrate RL-007's potential in CIAS, a major area of unmet patient need that presently lacks approved therapies."

Following these promising findings, atai has committed to initiate a randomized, double-blind, placebo-controlled, proof-of-concept Phase 2 study of RL-007. In addition to symbol coding and HVLT, this trial will also include other cognitive tests taken from the MCCB.

Schizophrenia is a mental health disorder affecting over 21 million people globally and approximately 3.5 million people in the United States.[5,6] While some symptoms, like delusions and hallucinations can be managed with antipsychotic medications, over 80% of patients suffer from significant cognitive impairment, which has no approved treatment and can be severely debilitating.[7,8] Such cognitive deficits contribute significantly to the disability associated with this condition, impacting the ability of those with schizophrenia to carry out basic tasks necessary for independent living.[9]

RL-007 Key Opinion Leader Event, January 18, 2022

atai will host an event featuring a presentation by Richard S.E. Keefe, PhD, of Duke University. Dr Keefe will discuss the current treatment landscape and unmet medical need in treating patients with CIAS, and will be followed by Matthew Pando, PhD, CEO and Co-Founder of Recognify Life Sciences, who will discuss the design of this recently completed Phase 2a trial for RL-007 and the preliminary topline data. The event is scheduled for January 18, 2022, at 12 PM ET. You are required to register in advance for the webcast, here. For those who are unable to listen at this time, a replay of the call will be available by clicking here.

About the RL-007 Phase 2a trial

The Phase 2a trial was a single-arm, single blind, multiple-dose study of oral RL-007 administered to subjects with schizophrenia. A total of four, 8-patient cohorts (32 subjects in total) were enrolled, testing the 10mg, 20mg, 40mg, and 80mg doses of RL-007, administered 3 times/day. Patients enrolled had to be on a stable dosing regimen of a protocol-allowed antipsychotic regimen, and they continued their antipsychotic treatment without change throughout the course of this study. All subjects received four doses of placebo followed by six doses of RL-007, although subjects were blinded to the dose strength and sequence of active and placebo capsules.

About RL-007

RL-007 is a neuromodulator that potently enhances synaptic plasticity by modulating excitatory neurotransmission and the cholinergic and gamma-aminobutyric acid type B (GABA type B) receptor systems, all of which are central to learning and memory functions. With its unique mechanism of action, atai believes RL-007 may enhance pro-cognitive functioning, such as neuronal signaling, learning, and memory.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. atai was 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.

atai's business model combines funding, technology, scientific and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders.

atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. atai has offices in New York, London, and Berlin. For more information, please visit www.atai.life.

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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 outcome of Recognify’s Phase 2a trial for its lead compound, RL-007, 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.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, 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; our product candidates contain controlled substances, the use of which may generate public controversy; 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 currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials and we expect this to continue upon approval, if any, of our current or future product candidates; if third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; 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; we face significant competition in an environment of rapid technological and scientific change; 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; a change in our effective place of management may increase our aggregate tax burden; we identified material weaknesses in connection with our internal control over financial reporting; 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. Other risk factors include the important factors described in the section titled “Risk Factors” in our final prospectus, dated June 17, 2021, filed with the Securities and Exchange Commission (“SEC”) pursuant to Rule 424(b) under the Securities Act, and in our other filings with the SEC, that may cause our actual results, performance or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements.

Any forward-looking statements made herein speak only as of the date of this press release, and you should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, performance, or achievements reflected in the forward-looking statements will be achieved or will occur. 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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