



atai Life Sciences Announces Supportive Interim Data from First 8-Patient Cohort of Phase 2a Trial for Novel Treatment of Cognitive Impairment Associated with Schizophrenia

November 1, 2021

These data have given atai confidence to support an accelerated clinical development timeline

NEW YORK, Nov. 01, 2021 (GLOBE NEWSWIRE) -- atai Life Sciences (Nasdaq: ATAI) ("atai") today announced that it has observed encouraging interim data from the first 8-patient cohort of its Phase 2a trial, demonstrating potential pro-cognitive effects of its compound RL-007, a cholinergic, glutamatergic, and GABA type B receptor modulator, for Cognitive Impairment Associated with Schizophrenia (CIAS).

These early data have led atai to commit additional financial resources, enabling an accelerated clinical development timeline for RL-007, even ahead of completion of the ongoing Phase 2a trial.

The interim Phase 2a readout reported promising assessments for the 8-patient cohort from two quantitative biomarkers, qEEG (quantitative electroencephalogram) and ERP (evoked-response potential) and indicated changes that are consistent with improved cognition. CIAS is a major unmet need for those living with schizophrenia, with no effective treatments currently available.¹ Full results of the current Phase 2a trial are expected by the end of 2021.

The financial boost by atai will enable immediate initiation of planning stages for the next clinical trial, ahead of schedule and prior to the Phase 2a's conclusion. The atai RL-007 trials are being conducted by Recognify Life Sciences, an atai Life Sciences platform company.

"With these data, from the interim analysis of the ongoing Phase 2a trial, we are encouraged to accelerate the overall development of RL-007 for CIAS," said Matthew Pando, PhD, CEO and Co-Founder of Recognify Life Science. *"I would like to express my deepest gratitude to the patient volunteers who have supported our clinical trial thus far. I believe that, with continued support, we have the potential to bring benefit to patients living with schizophrenia and its often very challenging cognitive impacts."*

"We believe that, although preliminary, these promising data give us confidence to further support and expedite the clinical trajectory for RL-007 and we look forward to the full data set," said Florian Brand, CEO and Co-Founder of atai Life Sciences. *"With its unique mechanism of action, we think that RL-007 has potential to address a major unmet need in terms of addressing the cognitive deficits that can be so debilitating for people with schizophrenia."*

Schizophrenia is a mental health disorder primarily characterized by hallucinations, delusions, and disordered thinking. This condition effects over 21 million people globally and approximately 3.5 million people in the United States.^{2,3}

CIAS is a major unmet need for those living with schizophrenia. Cognitive deficits are frequently present in patients diagnosed with schizophrenia, and such deficits contribute to the marked disability associated with this condition, impacting the ability of patients to carry out some basic living tasks, like pursuing education and holding down a job.⁴

About the RL-007 Phase 2a trial

The ongoing Phase 2a trial is a single-arm, single blind, multiple dose study of oral RL-007 administered to subjects with schizophrenia who are currently stable on a protocol-allowed antipsychotic regimen. Subjects continue their antipsychotic treatment without change throughout the course of this study. All subjects receive four doses of placebo followed by six doses of RL-007, although subjects are blinded to the dose strength or sequence of active and placebo capsules.

About RL-007

RL-007 has a unique mechanism of action, impacting both cholinergic and gamma-aminobutyric acid type B (GABA type B) receptor systems, which are both central to learning and memory functions. With its unique mechanism of action, we believe 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 mission is to bridge the gap between what the mental healthcare system currently provides and what patients need. atai has offices in New York, London, and Berlin. For more information, please visit www.atai.life.

References:

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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. Forward-looking statements include express or implied statements relating to, among other things, statements regarding the potential outcome of Recognify's ongoing 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; the commercialization of our current product candidates and any other product candidates that we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates that we may identify and pursue; the timing of, and our ability to obtain and maintain, regulatory approvals; our business strategy and plans; potential acquisitions; and the plans and objectives of management for future operations 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 discussed under the caption "Risk Factors" in atai's prospectus pursuant to Rule 424(b) filed with the U.S. Securities and Exchange Commission ("SEC") on June 21, 2021, and in atai's other filings with the SEC. 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 atai believes 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. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release (or to conform these statements to actual results or revised expectations), other than to the extent required by applicable law.

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