atai Life Sciences Initiates Phase 2b proof-of-concept trial of RL-007 for Cognitive Impairment Associated with Schizophrenia

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- The phase 2b proof-of-concept trial will evaluate the novel compound, RL-007, for pro-cognitive effects in patients with Cognitive Impairment Associated with Schizophrenia (CIAS).
- The trial was initiated and has begun patient screening this month with first-patient-in anticipated by end-of-year.
- There are currently no FDA-approved medications for CIAS, a major cause of disability in 80% of patients with schizophrenia[1].
- Topline results are expected in the first half of 2024.

NEW YORK and BERLIN, Dec. 19, 2022 (GLOBE NEWSWIRE) -- Today, atai Life Sciences N.V. (Nasdaq: ATAI) (“atai”), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, announced the initiation of its Phase 2b proof-of-concept clinical trial for RL-007 for Cognitive Impairment Associated with Schizophrenia (CIAS), a condition for which there are currently no FDA-approved treatments.

The Phase 2b trial is a randomized, placebo-controlled, double-blind, 3-arm study evaluating 2 doses of RL-007 and a placebo among 234 patients. The trial includes a 6-week treatment period with the MATRICS Consensus Cognitive Battery (MCCB) as the primary endpoint. The MCCB has been supported by the FDA as an approvable endpoint for CIAS. The trial will be conducted in the US, and patient screening is currently underway.

RL-007 is an orally available compound that modulates cholinergic, glutamatergic and GABA-B receptors, thereby putatively altering the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. It has previously been evaluated in ten clinical studies, including one in the CIAS indication, with over 500 unique participants dosed to-date.

In December 2021, atai announced positive biomarker data from a Phase 2a proof-of-mechanism study designed to evaluate the effects of RL-007 on safety, tolerability, electroencephalogram-based biomarkers, and cognition. RL-007 was well tolerated and demonstrated a clinically meaningful pro-cognitive profile consistent with previous Phase 1 and Phase 2 trials of this compound. These results supported the progression of an RL-007 Phase 2b proof-of-concept trial with the goal of demonstrating the pro-cognitive effect of RL-007 in CIAS.

Schizophrenia affects approximately 24 million people worldwide. The disease is frequently associated with significant distress and impairment in personal, family, social, educational, occupational, and other important areas of life. For example, cross-sectionally, only 10% of patients with schizophrenia are employed in a competitive role[2]. Furthermore, they are 2 to 3 times more likely to die early compared to the general population[3]. 80% of people with schizophrenia suffer from cognitive impairments, which include poor learning and retention of verbal information, as well as the most consistent findings of executive functioning deficits and an impaired ability to encode and retain verbally presented information[4].

“Schizophrenia is a debilitating neurological disease that can reduce life expectancy by almost 20 years. What’s worse is only about 30% of people with psychosis receive specialist mental health care,” commented atai Co-Founder and CEO Florian Brand. “The safety profile and positive pro-cognitive efficacy of RL-007 show promise for the significant unmet needs of people suffering from schizophrenia.”

“RL-007’s unique pharmacology as a GABA/nicotinic modulator, acute onset of action, and excellent tolerability profile differentiates it from competitor pipeline options,” stated Srinivas Rao, atai Co-Founder and Chief Scientific Officer. “It has the potential for complimentary use with antipsychotics. We look forward to the Phase 2b results anticipated H1 2024.”

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.

atai Life Sciences’ subsidiary, Recognify Life Sciences, is conducting this study. 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 Recognify Life Sciences and future activities thereunder; the potential of 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;

available funding under the Hercules Capital, Inc. loan facility; 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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[1] Bora E., et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM -V Criteria and Beyond. Schizophr Bull. 2010 Jan;36(1):36-42. doi: 10.1093/schbul/sbp094. Epub 2009 Sep 23.

[2] Marwaha S, Johnson S, Bebbington P, et al. Rates and Correlates of Employment in People with Schizophrenia in the UK, France and Germany. Br J Psychiatry. 2007;191(1):30-37.

[3] World Health Organization, 10 January 2022

[4] Bowie CR, Harvey PD. Cognitive Deficits and Functional Outcome in Schizophrenia. Neuropsychiatr Dis Treat. 2006 Dec;2(4):531-6. doi: 10.2147/nedt.2006.2.4.531. PMID: 19412501; PMCID: PMC2671937.