atai Life Sciences Company, Perception Neuroscience, Completes Enrollment for Phase 2a Clinical Trial of PCN-101 (R-Ketamine) for Treatment-Resistant Depression

October 25, 2022

- *Completed enrollment of Phase 2a proof-of-concept, randomized, double-blind, placebo-controlled clinical trial of PCN-101 (R-ketamine).*
- *Last patient expected to be dosed this week, with the total number of patients expected to be around 100. Topline results expected around year-end 2022.*
- *PCN-101 is being investigated as a potentially rapid-acting therapeutic for treatment-resistant depression (TRD) with at-home administration.*
- *atai to contextualize the upcoming Phase 2a topline results at its R&D Day today at 12 pm E.T.*

NEW YORK and BERLIN, Oct. 25, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company focused on developing innovative therapies for neuropsychiatric diseases and its subsidiary, Perception Neuroscience ("Perception"), today announced the completion of enrollment of its Phase 2a clinical trial to evaluate the safety and efficacy of a single intravenous infusion (IV) dose of PCN-101 (R-ketamine). R-ketamine is a stereoisomer of ketamine being developed for treatment-resistant depression (TRD). TRD patients are partially or entirely unresponsive to antidepressants and face issues of misdiagnosis, prolonged depressive periods, co-occurring mental and physical disorders, and longer periods with a lower quality of life than patients suffering from less severe depression.

The Phase 2a proof-of-concept trial is a randomized, double-blind, placebo-controlled study with an enrollment target of 93 TRD patients across three arms. The last patient is expected to be dosed this week, with the total number of patients expected to be around 100. These patients – all of whom had previously failed at least two rounds of antidepressants – received either a single dose of placebo, 30 mg, or 60 mg of PCN-101 via IV in addition to their existing treatment regimen. Patients were assessed for a change in depressive symptomatology using the Montgomery-Asberg Depression Rating Scale (MADRS) at intervals over 14 days, with the primary endpoint at 24 hours post-dose. Dissociation and sedation were measured using the Clinician-Administered Dissociative States Scale (CADSS) and the Modified Observer's Alertness/Sedation Scale (MOAA/S), respectively.

"This is a critical study and the first to assess the efficacy, tolerability, and duration of action of PCN-101 in a double-blind manner. We look forward to sharing the topline results around year-end," said Maju Mathews, MD, Chief Medical Officer of Perception. "We are working diligently to initiate our next study comparing the intravenous to the subcutaneous formulation."

"I am very proud of the Perception team and our partners for reaching this critical milestone in our program to explore the potential of PCN-101 for people living with TRD. In addition, I am grateful to the patients who took the time and effort to participate in the study," said Terence Kelly, Ph.D., CEO of Perception Neuroscience. "An estimated 100 million people worldwide live with TRD. These patients are more likely than those with milder depression to experience serious complications, ranging from physical comorbidities to suicidal ideation and suicide attempts. PCN-101 has the potential to offer those with TRD a rapid-acting antidepressant that can be administered in the home."

"Completing enrollment of this Phase 2a trial is an important achievement and represents a major step towards potentially delivering a novel care option for mental health patients with unsupervised, at-home administration," added Florian Brand, Co-Founder, and CEO of atai Life Sciences. "Changing the treatment landscape for TRD may not only alleviate the suffering of the 100 million people living with TRD around the globe, but also decrease overall healthcare utilization, bringing us closer to realizing our vision of healing mental health disorders so that everyone, everywhere can live a more fulfilled life."

atai will be hosting a virtual R&D Day today, October 25, at 12 pm ET, during which it will discuss the PCN-101 program and contextualize the upcoming Phase 2a readout, among other topics. Click here or visit our website for more information: https://ir.atai.life/news-events/events.

About PCN-101
Perception Neuroscience is developing PCN-101 (R-ketamine) for the treatment of treatment-resistant depression. PCN-101 is a single isomer of ketamine and belongs to a new generation of glutamate receptor modulators with the potential for rapid-acting antidepressant (RAAD) activity and anti-suicidal effects. Pharmacologically, PCN-101 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. Nonclinical depression model studies in rodents suggest that R-ketamine could possess more durable and potent effects than S-ketamine despite a lower affinity to the NMDA receptor and potentially a more favorable safety and tolerability profile.

About Perception Neuroscience, Inc
Perception Neuroscience is a New York City-based clinical-stage biopharmaceutical company committed to developing therapies for neuropsychiatric diseases. Perception's mission is to provide more effective treatment solutions for serious psychiatric disorders. The company is a majority-owned subsidiary of atai Life Sciences.

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 Perception Neuroscience and future results and activities thereunder; the potential of PCN-101; 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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