# atai Life Sciences Announces Results from Phase 2a Trial of PCN-101 (R-ketamine) for Treatment-Resistant Depression

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NEW YORK and BERLIN, Jan. 06, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) (“atai” or “the Company”), a clinical-stage biopharmaceutical company focused on mental health, announced that, while PCN-101 (R-ketamine) demonstrated signals of efficacy across all timepoints out to two weeks, Perception Neuroscience’s Phase 2a clinical trial did not meet its primary endpoint of a statistically significant change from baseline in participants’ MADRS (Montgomery-Åsberg Depression Rating Scale) score at 24 hours compared to placebo.

The Phase 2a proof-of-concept trial was a two-week, randomized, double-blind, placebo-controlled multi-center study assessing the safety, tolerability and efficacy of a single IV administration of PCN-101. 102 TRD patients were enrolled across three arms – 30mg, 60mg and placebo.

On the primary endpoint of MADRS at 24 hours, the mean change from baseline was -15.3 for PCN-101 60mg compared to -13.7 for placebo (-1.6 pbo-adj; p-value 0.5). However, the single 60mg dose of PCN-101 showed an efficacy signal at each timepoint over the 2-week timeframe of the study.

Key secondary endpoints included a proportion of patients defined as responders, meaning patients who experienced 50% improvement from baseline in MADRS, and a proportion of patients in remission, defined as a total MADRS score of less than 10. Despite seeing greater response and remission rates in the 60mg arm, the trial did not meet statistical significance at any timepoint on these secondary measures.

PCN-101 was generally well-tolerated with rates of sedation and dissociation comparable to placebo.

“We thank all the patients, families, caregivers, and investigators for their support and participation in the PCN-101 Phase 2a trial,” said Florian Brand, CEO and Co-Founder of atai.

PCN-101 demonstrated an encouraging safety profile and signals of efficacy across all timepoints despite not achieving statistical significance on the primary endpoint. atai will further evaluate the PCN-101 data in more detail over the next weeks and will work with its subsidiary Perception Neuroscience to explore next steps, including but not limited to seeking strategic partnership options.

**PCN-101 Phase 2a Study Design**

The Phase 2a proof-of-concept trial was a randomized, double-blind, placebo-controlled multi-center study assessing the safety, tolerability and efficacy of IV PCN-101 (R-ketamine) in 102 patients with TRD across three arms. These patients – all of whom had previously failed at least two rounds of antidepressants – received a single IV dose of either placebo, 30 mg, or 60 mg of PCN-101 adjunctively to their existing treatment regimen.

Patients were assessed for a change in depressive symptomatology using the Montgomery-Åsberg 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.

**About Perception Neuroscience, Inc**

Perception Neuroscience is a New York City-based clinical-stage biopharmaceutical company committed to the mission of providing more effective treatment solutions for serious psychiatric disorders. It is developing PCN-101 (R-ketamine) for the treatment of TRD. In March 2021, the company announced a collaboration and licensing agreement with Otsuka Pharmaceutical Co., Ltd. for rights in Japan to PCN-101. Perception Neuroscience 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. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). 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. All statements in this press release other than statements of historical fact are forward-looking statements, including, express or implied statements relating to, among other things: statements regarding the trials, results and our expectations related to any subsequent steps concerning the PCN-101 (R-ketamine) studies, data, or related plans and objectives of management for future operations, capital expenditures and capital allocation. 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”) as further updated in our Quarterly Reports on Form 10-Q and 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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