atai Life Sciences Announces Results from the Phase 1 IV-to-Subcutaneous Bridging Study of PCN-101 (R-Ketamine)

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NEW YORK and BERLIN, Aug. 08, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) (“atai”), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, announced results from Perception Neuroscience’s Phase 1 intravenous-to-subcutaneous bridging study of PCN-101 (R-ketamine).

The Phase 1 open-label, 4-period crossover study assessed the safety, tolerability, and pharmacokinetic profile of 60mg, 90mg and 120mg of PCN-101 delivered subcutaneously (“SQ”) as compared to 60mg of PCN-101 delivered intravenously (“IV”). The study enrolled 16 healthy volunteers, each into one of four sequences of administration.

The study was designed to inform dosing regimens of the new subcutaneous formulation that may optimize the therapeutic index—the balance of safety, tolerability, and efficacy—of PCN-101 in future studies, thereby supporting further exploration of the potential of R-ketamine as a rapid acting anti-depressant for at-home use.

Pharmacokinetic (PK) analysis indicates that 120mg of PCN-101 delivered SQ resulted in an approximate doubling of drug exposure (AUC) while maintaining approximately the same maximum concentration (Cmax) as the 60mg IV dose.

Further, PCN-101 was generally well-tolerated with no serious adverse events reported. At the 60mg IV dose, rates of sedation and dissociation were consistent with prior studies of PCN-101 at this dose-level. Encouragingly, at the highest SQ dose of 120mg, rates of sedation (defined as MOAA/S[1] score <5) and dissociation (defined as CADSS[2] total score >4 and change from baseline >0) were each 14%.

While recognizing the limitations of this small bridging study and cross-trial comparisons, this safety and tolerability profile compares favorably to that of Spravato, for which rates of sedation and dissociation have been reported to be in the ranges of 50-61% and 61-69%[3], respectively, in prior studies. In addition, rates of sedation and dissociation were similar to those seen in the placebo arms of both the prior Phase 2 study of PCN-101 and the Spravato clinical trials in depression. Collectively, we believe these data support the concept of at-home use of PCN-101 in future studies.

atai continues to work with Perception Neuroscience to explore strategic partnership options.

1. Modified Observer’s Assessment of Alertness and Sedation 2. Clinician Administered Dissociative State Scale 3. SPRAVATO (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc 2020.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders and was founded as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to 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 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.

About Perception Neuroscience

Perception Neuroscience is a biopharmaceutical company committed to developing therapies for neuropsychiatric diseases. Perception’s mission is to provide substantially more effective treatment solutions to serious psychiatric disorders. The company is a majority-owned subsidiary of atai Life Sciences.

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 activity and anti-suicidal effects. Pharmacologically, PCN-101 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. Depression model studies in rodents suggest that R-ketamine could possess more durable effects than S-ketamine and a more favorable safety and tolerability profile.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “could,” “would,” “project,” “plan,” “potentially,” “preliminary,” “likely,” and the negative of these terms and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including without limitation our expectations and projections regarding the success, cost, and timing of development of PCN-101 (R-ketamine) and related studies; our business strategy and plans, including potential partnerships and other strategic arrangements; and the plans and objectives of management for future operations and capital expenditures.

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. Because forward-looking statements are subject to known and unknown risks uncertainties, and assumptions, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks uncertainties, and assumptions include, among others: our limited operating history, historical losses, and anticipation that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, including the development and any commercialization of our product candidates; 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 programs may experience delays or may never advance to clinical trials; our reliance on third parties to assist in conducting our clinical trials and impact to such trials based on factors including failure by third parties to meet trial or testing deadlines; our reliance on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates and failure to recruit and retain a sufficient number of therapists; the timing and outcome of regulatory review and/or approvals, which are necessary prior to commercialization; 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; significant competition; obtaining, maintaining and protecting our intellectual property; restricted operating activity as a result of covenants in any financing arrangements, including our loan agreement with Hercules Capital, Inc.; our aggregate tax burden based on our management and operational activity. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2023, as may be updated by other filings we file with or furnish to the SEC.

Any forward-looking statements made herein speak only as of the date of this press release. 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.

Contact Information Investors: atai Investor Relations IR@atai.life Media: atai Public Relations PR@atai.life