atai Life Sciences Announces First Subject Dosed in the Phase 1 IV-to-Subcutaneous Bridging Study of PCN-101 (R-Ketamine)

April 13, 2023

NEW YORK and BERLIN, April 13, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, announced that the first subject has been dosed in Perception Neuroscience's Phase 1 intravenous-to-subcutaneous bridging study of PCN-101 (R-ketamine).

This Phase 1 open-label study is designed to assess the safety, tolerability, and pharmacokinetic profile of 60mg, 90mg and 120mg of PCN-101 delivered subcutaneously as compared to 60mg of PCN-101 delivered intravenously (IV). The trial will enroll approximately 16 healthy volunteers across the four cohorts and is expected to be completed in the middle of 2023.

In January 2023, atai announced results from the Phase 2a proof-of-concept study evaluating a single IV administration of PCN-101 in patients with treatment-resistant depression across three arms – 30mg, 60mg and placebo. While the results did not reach statistical significance on the primary endpoint, PCN-101 demonstrated an encouraging safety profile and signals of efficacy across all timepoints out to two weeks, potentially indicating a sustained duration of effect.

This IV-to-subcutaneous bridging study will potentially 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.

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

About Perception Neuroscience, Inc.

Perception Neuroscience is a New York City- based 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 AG.

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.

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. 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"). All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including without limitation statements 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. These forward-looking statements are neither promises nor guarantees, and are subject to a number of important factors that could cause actual results to differ materially from any future results, performance or achievements 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 expect to incur losses for the foreseeable future and may never be profitable; if we are unable to obtain funding when needed and on acceptable terms, we could be forced to delay, limit or discontinue 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 rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing; we currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials and we expect this to continue upon approval, if any, of our current or future product candidates, and if third-party sites

fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed; our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; 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; the production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions; we face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before we do or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition; if we are unable to obtain and maintain sufficient intellectual property protection for our existing product candidates or any other product candidates that we may identify, or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our existing product candidates and any other product candidates that we may pursue may be impaired; 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; our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel; as a result of covenants to our loan agreement with Hercules Capital, Inc., our operating activities may be restricted and we may be required to repay the outstanding indebtedness in the event of a breach by us, or an event of default thereunder, which could have a materially adverse effect on our business; if we fail to maintain an effective system of disclosure controls and internal control over financial reporting our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired; our business is subject to economic, political, regulatory and other risks associated with international operations; 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, and other risks, uncertainties, and assumptions described under “Risk Factors” in Item 1A of Part I, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 of Part II and elsewhere in our Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

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 we believe 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. 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.

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