



Perception Neuroscience initiates Phase 2a study of PCN-101 (R-ketamine) for treatment resistant depression

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NEW YORK and BERLIN, Sept. 14, 2021 (GLOBE NEWSWIRE) -- Perception Neuroscience (Perception), an [atai Life Sciences](#) (atai) biopharmaceutical company focused on developing innovative therapies in neuropsychiatric diseases, today announced the initiation of a Phase 2a clinical study to evaluate the safety and efficacy of PCN-101 (R-ketamine). R-ketamine is a stereoisomer of ketamine being developed for therapeutic treatment of psychiatric disorders such as Treatment Resistant Depression (TRD). The Phase 2a clinical trial has received the necessary regulatory and ethics approvals to initiate the study.

The Phase 2a trial is a double blind, placebo-controlled study in patients with TRD. Each of the 3 parallel arms will enroll 31 patients at multiple locations. Patients will receive either placebo, a 30 mg dose, or a 60 mg dose of R-ketamine intravenously.

Patients will be assessed for depressive symptomology over the subsequent 14 days using the Montgomery-Asberg Depression Rate Scale, or MADRS. Topline data from the study is expected to be reported at the end of 2022.

"We're excited to take the next key step with this clinical trial to show the potential of PCN-101 for people living with TRD," said Terence Kelly, PhD, CEO of Perception Neuroscience. "TRD impacts nearly 100 million people around the world, making up a third of patients living with depression; currently they are either undertreated or unresponsive to existing treatment options. We believe PCN-101 holds promise in helping such treatment-resistant patients, as a potential rapidly-acting antidepressant which can be administered at home."

"We believe insight into the molecular properties of the single isomer, R-ketamine, has the potential to offer a highly differentiated profile from current treatment options," added Florian Brand, CEO & Co-founder of atai Life Sciences. "Initiating this Phase 2 clinical study is a major step for our teams at Perception and atai and is a great achievement. We believe this work has the potential to deliver a novel option with diversified delivery capabilities that could decrease overall healthcare utilization, which may help us move toward our greater mission to improve care for patients who suffer from TRD."

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 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.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. atai was 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's business model combines funding, technology, scientific, and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders. atai's mission is to bridge the gap between what the mental healthcare system currently provides and what patients need. atai has offices in New York, London, and Berlin. 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. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements, including without limitation statements regarding the initiation of the Phase 2a trial by Perception and future activities thereunder, the potential of PCN-101, and similar statements of a future or forward-looking nature. Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, including, without limitation, the important factors discussed under the caption "Risk Factors" in atai's prospectus pursuant to Rule 424(b) filed with the U.S. Securities and Exchange Commission ("SEC") on June 21, 2021, as such factors may be updated from time to time in atai's other filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof and accordingly undue reliance should not be placed on such statements. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, whether as a result of new information, future events or otherwise, other than to the extent required by applicable law.

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