



Perception Neuroscience's PCN-101 (R-Ketamine) Demonstrates Tolerability in Phase 1 Single Ascending Dose Study

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NEW YORK, Feb. 19, 2021 /PRNewswire/ -- Perception Neuroscience (Perception), an atai Life Sciences (atai) biopharmaceutical company focused on developing innovative therapies in neuropsychiatric diseases, today announced positive data from its first Phase 1 clinical study demonstrating the safety and tolerability of PCN-101 (R-ketamine). R-ketamine is a stereoisomer of ketamine that is being developed for therapeutic treatment of psychiatric illnesses such as Treatment Resistant Depression (TRD).

The two-stage study first evaluated the safety, tolerability and pharmacokinetics of single ascending doses of PCN-101 in 58 healthy adult volunteers, administered via intravenous infusion and compared to placebo. In this study, PCN-101 was safe and well-tolerated at all doses up to 150 mg, the highest dose tested. There were no serious adverse events reported. The pharmacokinetics of PCN-101 in plasma were approximately dose-proportional.

The second stage of the study compared the relative safety and tolerability of PCN-101 to that of S-ketamine. The results demonstrated that PCN-101 required substantially higher doses to induce similar perceptual changes than S-ketamine.

"We are excited by the Phase 1 results that support the hypothesis that PCN-101 can be developed as a rapidly acting antidepressant with the potential for at-home use," said Terence Kelly, PhD, CEO of Perception Neuroscience. "The upcoming Phase 2 proof-of-concept trial in patients with Treatment Resistant Depression is the next important step in demonstrating the full potential of PCN-101."

Dr. Kelly also announced that Perception has secured additional funding to enable the Phase 2a proof-of-concept study of PCN-101. This study is expected to initiate in the second quarter of 2021. The financing round was led by atai Life Sciences.

"The success of Perception's Phase 1 clinical study leads us to believe that PCN-101 has the potential to offer a highly differentiated profile from current treatment options," said Florian Brand, CEO & Co-founder of atai Life Sciences. "We are thrilled by this success, with these results paving the way for our upcoming Phase 2 clinical study. The incredible work of the teams at Perception and atai, combined with the support of our investors, provides progress in our mission of delivering optionality to patients who suffer from Treatment Resistant Depression."

About the Phase 1 study

This was a Phase 1 single-center, randomized, placebo-controlled, double-blind single ascending dose study of the safety, tolerability and pharmacokinetics of PCN-101 that included a subsequent relative safety comparison of PCN-101 and S-ketamine. Healthy subjects were administered a single 40-minute intravenous infusion of PCN-101 or placebo.

The safety and tolerability assessments included reported adverse events, changes in hematology, serum chemistry, vital signs, ECG, sedation, and the development of dissociative or perceptual changes.

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 biotechnology company that was founded in 2018 as a direct response to the significant and growing unmet needs of mental health patients worldwide. atai is pioneering the development of more effective and potentially-disease modifying mental health treatments for patients suffering from significant unmet medical needs. 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 business entities, 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 is headquartered in Berlin, with offices in New York and San Diego. For more information, please visit www.atai.life.

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Forward Looking Statements:

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments, and strategies. The forward looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, our expectations regarding the potential therapeutic benefits of PCN-101, our plans to initiate a Phase 2 trial evaluating PCN-101 as a potential treatment for Treatment Resistant Depression (TRD) and a Phase 2a proof-of-concept study evaluating PCN-101 in patients with TRD, our plans to advance PCN-101 for the treatment of TRD and those risks and uncertainties described in the risk factors included in the regulatory filings for Perception Neuroscience, Inc. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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