

Perception Neuroscience And Otsuka Pharmaceutical Announce Collaboration On Development Of PCN-101 (R-ketamine) In Japan For Treatment-of Depressive Disorders

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NEW YORK and TOKYO, March 16, 2021 /PRNewswire/ -- Perception Neuroscience (Perception), an atai Life Sciences (atai) company focused on developing innovative therapies in neuropsychiatric disorders, and Otsuka Pharmaceutical Co., Ltd. (Otsuka), announce a collaboration and licensing agreement for the development and commercialization of Perception's lead molecule, PCN-101 (R-ketamine) in Japan as a potential treatment for mood disorders such as major depressive disorder (MDD) and treatment-resistant depression (TRD). Outside of Japan, Perception is developing PCN-101 for the treatment of treatment-resistant depression.

PCN-101 is a formulation of R-ketamine, a single isomer of ketamine that belongs to a new generation of glutamate receptor modulators, being developed as a rapid acting antidepressant (RAAD). Pharmacologically, PCN-101 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. In nonclinical depression models it possessed more durable and potent effects than S-ketamine, a lower affinity to the NDMA receptor, and potentially a more favorable safety and tolerability profile. A Phase 1, single ascending dose study has been completed for PCN-101 and a Phase 2 proof-of-concept study in TRD is planned to be initiated by Perception in the first half of 2021.

Under the terms of the license, Otsuka will have exclusive rights to develop and commercialize products containing PCN-101 in Japan. Otsuka will undertake development, regulatory, and commercialization activities in Japan, with input and guidance from both companies. Perception will receive an upfront payment of \$20 million, which will help fund the company's overall development of treatments. In addition, Perception will be eligible to receive development, regulatory and commercial milestones, as well as tiered, double-digit royalties on future sales.

"Otsuka is one of the world's premier pharmaceutical companies in the neuropsychiatric space." said Terence Kelly, PhD, CEO of Perception. "To have such a strong collaborator at this early stage of development is a significant vote of confidence in the potential of PCN-101 for patients suffering from depression."

Florian Brand, CEO and co-founder of atai, said, "Otsuka is dedicated to finding unconventional solutions to treat mental health disorders with a deepening focus on digital medicine. Its innovative approach to mental health paired with their experience in commercializing neuropsychiatric drugs as demonstrated by the successful roll-out of products such as Rexulti and Abilify Maintena, makes Otsuka a great company for us to work with. We look forward to working together with them on Perception's lead compound".

Makoto Inoue, president of Otsuka Pharmaceutical, remarked, "We have a long and deep engagement in the CNS field, including our in-line products Rexulti, Abilify Maintena, and specific to the U.S, the first-in-the-world digital medicine, Abilify Mycite. Looking to the future, Perception Neuroscience's PCN-101, a candidate with rapid onset for use in treatment-resistant depression, could provide an urgently needed treatment option. Perception Neuroscience is uniquely positioned to work with us in Japan on this urgent task."

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 is headquartered in Berlin, with offices in New York, San Diego and London. For more information, please visit <u>www.atai.life</u>.

About Otsuka

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: "Otsuka–people creating new products for better health worldwide." Otsuka researches, develops, manufactures, and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging areas of mental, renal and

cardiovascular health and has additional research programs in oncology and on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately USD 13.3 billion in 2020.

All Otsuka stories start by taking the road less traveled. Learn more about Otsuka at www.otsuka.co.jp/en/.

Investor Contact:

Greg Weaver atai – Chief Financial Officer Email: <u>greg.weaver@atai.life</u>

Media Contact:

Anne Donohoe KCSA Strategic Communications Phone: +1 (212) 896-1265 Email: <u>atai@KCSA.com</u>

<u>Otsuka contact in Japan</u>: Jeffrey Gilbert

Leader, Pharmaceutical PR Email: <u>Gilbert.jeffrey@otsuka.jp</u>

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 and conduct a Phase 2a proof-of-concept study evaluating PCN-101 as a potential treatment for treatment-resistant depression (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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