

Cyclerion Therapeutics Announces Publication of CY6463 Preclinical Data in Frontiers in Pharmacology

May 27, 2021

Series of preclinical studies demonstrate the therapeutic potential of CY6463, a first-in-class, CNS-penetrant sGC stimulator

Oral, once-daily CY6463 is being developed for neurological diseases associated with cognitive impairment

CAMBRIDGE, Mass., May 27, 2021 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN) today announced the <u>publication</u> of preclinical data of CY6463 in Frontiers in Pharmacology. Cyclerion is developing CY6463, an oral, first-in-class, central nervous system (CNS)-penetrant sGC stimulator, for neurological diseases associated with cognitive impairment, including Alzheimer's disease with vascular pathology (ADv), Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS), as well as Cognitive Impairment Associated with Schizophrenia (CIAS).

Cyclerion identified and developed CY6463 based on its ability to readily access the CNS and amplify nitric oxide-soluble guanylate cyclase-cyclic guanosine monophosphate (NO-sGC-cGMP) signaling in the brain. CY6463 was designed to address multiple pathophysiological features of neurodegenerative and neuropsychiatric diseases associated with cognitive impairment.

Extensive preclinical data from CY6463 and decades of research validate the crucial role of the sGC pathway in brain physiology and cognition. Across a range of preclinical models, administration of CY6463 resulted in physiologically relevant drug levels in cerebrospinal fluid (CSF) and led to improvements in neuronal function, neuroprotection, and cognitive performance. Together, these data further support the clinical development of CY6463 as a novel and potentially paradigm-shifting approach to the treatment of neurodegenerative and neuropsychiatric disorders.

Results from initial CY6463 clinical studies have demonstrated favorable safety and tolerability and pharmacologically relevant exposure in the CSF. In addition, CY6463 resulted in promising impacts on brain cortical oscillations, neuroinflammation, and other neurophysiological measures that support continued clinical development.

Cyclerion has an active Phase 2 study of CY6463 in participants with MELAS and the Company is planning to initiate additional Phase 2 studies in individuals with ADv and CIAS.

About Cyclerion Therapeutics

Cyclerion Therapeutics is a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function. Cyclerion is advancing novel, first-in-class, CNS-penetrant, sGC stimulators that modulate a key node in a fundamental CNS signaling pathway. The multidimensional pharmacology elicited by the stimulation of sGC has the potential to impact a broad range of CNS diseases. The most advanced compound, CY6463, has shown rapid improvement in biomarkers associated with cognitive function and is currently in clinical development for Alzheimer's Disease with Vascular pathology (ADv), Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS), and Cognitive Impairment Associated with Schizophrenia (CIAS). Cyclerion is also advancing CY3018, a next-generation sGC stimulator.

For more information about Cyclerion, please visit https://www.cyclerion.com/ and follow us on Twitter (@Cyclerion) and LinkedIn (www.linkedin.com/company/cyclerion).

Forward Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks listed under the heading "Risk Factors" and elsewhere in our 2020 Form 10-K filed on February 25, 2021, and our subsequent SEC filings including the Form 10-Q filed on April 30, 2021. Investors are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Cyclerion undertakes no obligation to update these forward-looking statements, except as required by law.

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Source: Cyclerion Therapeutics, Inc.