Cyclerion Therapeutics Announces Global Licensing Agreement with Akebia Therapeutics for Praliciguat

June 4, 2021

Cyclerion eligible to receive up to $585 million in potential future development and commercial milestone payments, and tiered sales-based royalties

Praliciguat out-licensing further enables Cyclerion's strategic focus on CNS, including first-in-class CNS-penetrant sGC stimulators CY6463 and CY3018

CAMBRIDGE, Mass., June 04, 2021 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN) today announced that it has entered into an exclusive, global license agreement with Akebia Therapeutics, Inc., a leading biopharmaceutical company focused on kidney disease, for the development and commercialization of praliciguat, an oral sGC stimulator.

Under the terms of the agreement, Akebia has obtained an exclusive license to research, develop and commercialize praliciguat globally and will be solely responsible for these activities going forward. Cyclerion is eligible to receive up to $225M in pre-commercial milestones, including up to $15M in the first 18 months. Total potential future development, regulatory, and commercialization milestone payments could result in up to $585M. Cyclerion is also eligible to receive tiered, sales-based royalties ranging from single-digit to high-teen percentages.

"We are very pleased to license praliciguat to Akebia, whose demonstrated leadership in kidney disease and extensive R&D and commercialization capabilities make it an ideal partner for the future development of praliciguat. This transaction provides Cyclerion with meaningful participation in any potential near and longer-term value creation and enables us to focus on our mission to develop treatments for cognitive impairment, including our foundational assets CY6463 and CY3018, where we see enormous clinical promise," said Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion.

"We are pleased to expand our clinical development pipeline with the in-licensing of praliciguat, which is highly complementary of our strategy to identify and efficiently develop novel therapeutics for people impacted by kidney disease," said John P. Butler, Chief Executive Officer of Akebia Therapeutics, Inc. "We look forward to leveraging our capabilities to explore development and commercialization of praliciguat."

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. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the uncertain utility, development, promise, and commercialization of praliciguat; and whether any of the referenced or other development, regulatory, and commercialization milestones or royalty payments provided for in the license agreement with Akebia will be achieved. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability of any party to raise the funding needed to pursue business and product development plans; the inherent uncertainties associated with developing new products or technologies; the ability to develop, complete clinical trials for, obtain approvals for and commercialize any product candidates, including the ability to recruit and enroll patients in appropriate studies; the ability to address the requests of the U.S. Food and Drug Administration and similar regulators in other jurisdictions; and market conditions. 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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