



Cyclerion Announces Phase 2 STRONG-SCD Study Results in Patients with Sickle Cell Disease

October 14, 2020

Study results do not support further internal development

CAMBRIDGE, Mass., Oct. 14, 2020 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company, today announced top-line results from its STRONG-SCD study of olinciguat, an investigational, orally-administered, once daily, vascular sGC stimulator for the potential treatment of sickle cell disease (SCD). Olinciguat was generally well tolerated across all dose ranges. Results did not demonstrate adequate activity to support further internal clinical development. Cyclerion intends to complete its analysis of the study results and present or publish them in a future forum.

"We would like to thank all of the sickle cell patients who participated in the STRONG-SCD study, the SCD advocacy community, and the investigators and study staff who focused their time and efforts on helping us better understand the potential of olinciguat in sickle cell disease," said Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion. "While we are disappointed that we won't be contributing a much-needed new treatment option for SCD, we are continuing to analyze the data to understand several potential biomarker signals, including inflammation, as we explore partnership options for this program."

As described in the Company's IW-6463 press release also issued today, Cyclerion expects to be focused on the development of treatments for serious diseases of the central nervous system (CNS).

About STRONG-SCD Study

The STRONG-SCD study is a randomized, placebo-controlled, dose-ranging Phase 2 study of 70 participants designed to evaluate safety, tolerability, and pharmacokinetics of olinciguat, compared to placebo, as well as to explore effects on daily symptoms and biomarkers of disease activity when dosed over a 12-week treatment period.

About Cyclerion Therapeutics

Cyclerion Therapeutics is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing innovative medicines for people with serious diseases of the central nervous system (CNS). Cyclerion's lead program is IW-6463, a pioneering CNS-penetrant sGC stimulator in clinical development for Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS) and Alzheimer's Disease with Vascular pathology (ADv).

For more information about Cyclerion, please visit <https://www.cyclerion.com/> and follow us on Twitter ([@Cyclerion](https://twitter.com/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, including statements about the results and conduct of our Phase 2 proof-of-concept clinical trial of olinciguat; our interpretation of the data from the clinical trial; the potential further evaluation of olinciguat; the potential strategic options for olinciguat; the clinical potential of olinciguat; our future business focus; advancing our other clinical trials; and the business and operations of Cyclerion. 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. 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. Applicable risks and uncertainties include the risks listed under the heading "Risk Factors" and elsewhere in our 2019 Form 10-K filed on March 12, 2020, and in Cyclerion's subsequent SEC filings, including the Form 10-Q filed on May 4, 2020 and the Form 10-Q filed on August 3, 2020.

Investors

Carlo Tanzi, Ph.D.
Kendall Investor Relations
ctanzi@kendallir.com

Media

Amanda Sellers
Verge Scientific Communications
asellers@vergescientific.com



Source: Cyclerion Therapeutics, Inc.