# Cyclerion Therapeutics Reports Third Quarter 2020 Financial Results and Recent Corporate Updates

November 5, 2020

*Positive IW-6463 translational pharmacology study in healthy elderly subjects showed significant improvements in multiple measures associated with age-related cognitive decline and neurodegenerative diseases*

*Company revamping its organization to focus on critical IW-6463 CNS program priorities; expects 2021 average cash use reduction of approximately 50% from Q3 2020 levels*

*Company anticipates that its current cash will be sufficient to fund its current CNS priorities, including the MELAS and ADv studies, and further characterization of IW-6463 novel pharmacology*

*MELAS study expected to initiate in Q4 2020 with top-line readout in mid-2021 and the ADv study expected to initiate in 2021*

CAMBRIDGE, Mass., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company developing innovative medicines for people with serious diseases of the central nervous system (CNS), reported financial results for the third quarter ended September 30, 2020 and provided general corporate and pipeline updates.

"We are highly encouraged by the data from our IW-6463 translational pharmacology study showing robust and consistent positive effects on multiple measures of brain neurophysiology that are associated with age-related cognitive decline and neurodegenerative diseases," said Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion. "IW-6463 is a promising new approach for CNS diseases that have very limited therapeutic options today. Building on the exciting IW-6463 translational pharmacology study results and leveraging our team's neuroscience expertise, the Company will concentrate on developing meaningful treatments for serious CNS diseases. Our immediate priority is to rapidly and efficiently further assess the clinical profile of IW-6463, and we look forward to initiating enrollment in our MELAS study this quarter and in our ADv study in 2021."

**Recent Program and Business Updates**

- **IW-6463 Program Update:** Cyclerion announced promising results from its Phase 1 translational pharmacology study of IW-6463, the first soluble guanylate cyclase (sGC) stimulator in clinical development for CNS disorders.

  Treatment with IW-6463 in the 15-day 24-subject crossover study confirmed and extended results seen in the earlier Phase 1 study: once daily oral treatment demonstrated blood-brain-barrier penetration, desired CNS exposure levels, target engagement and showed IW-6463 to be safe and generally well-tolerated. In this study, subjects receiving IW-6463 showed improvements in several neurophysiological and objective performance measures that are associated with age-related cognitive decline and neurodegenerative diseases. Effects on cerebral blood flow and markers of bioenergetics were not observed in this study of healthy elderly subjects.

  These results support the ongoing development of IW-6463 in serious CNS diseases. Cyclerion expects to begin enrolling its Phase 2 clinical trial in patients with Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like episodes (MELAS) this quarter. The Company will use the findings of the translational pharmacology study, in addition to observations from the previous Phase 1 study of 110 healthy subjects, to inform further clinical development activities, including the initiation of a planned Phase 2 clinical trial in Alzheimer's disease with vascular pathology (ADv) in 2021, as well as to explore other potential indications.

  In July, the Company announced that it has been awarded a grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program. This award will support the Company's upcoming Phase 2 trial of IW-6463 in ADv. The award provides Cyclerion with $2 million of funding over the next 2 years.

- **Sickle Cell Program Update:** The Company 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 doses. 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 medical forum.

- **Praliciguat Update:** The Company is working to out-license rights to praliciguat, its orally administered, once-daily systemic sGC stimulator, and has expanded to discussions beyond treatment of cardiometabolic disorders to include additional indications where sGC stimulators have demonstrated efficacy.

- **Financing:** On July 29, Cyclerion announced a private equity investment of $24 million. On September 3, 2020, the Company entered into a Sales Agreement with Jefferies LLC with respect to an at-the-market offering (ATM Offering) which allows the sale of up to $50M of shares from time to time over the next three years at the open market price. As of September 30, 2020, no shares have been issued or sold under the ATM Offering.

- **Strategic Update and Organization Restructuring**: Consistent with its previously announced intent to focus on developing treatments for serious CNS diseases, Cyclerion's investments will be directed to fund its current CNS priorities, including the upcoming MELAS study, the planned ADv study and further characterization of IW-6463 pharmacology. The Company will revamp its organization beginning immediately to align with these priorities. The Company expects to take an aggregate charge for one-time employee-related costs of approximately $5 million that is expected to be incurred primarily in Q4 2020 and realize annual cash savings of approximately $10 million. The Company also intends to exit its current laboratory and office facilities in early 2021, from which it expects annual cash savings of about $10 million. These and other spending reductions are expected to lower the Company's average quarterly cash use in 2021 by about 50% from the Q3 2020 level of approximately $15 million. The Company anticipates that its current cash will be sufficient to fund its current CNS priorities, including the ongoing MELAS study, the planned ADv study and further characterization of IW-6463 pharmacology.

- **Transition of President and Chief Scientific Officer**: Dr. Mark Currie, Cyclerion's President and Chief Scientific Officer (CSO), will transition at year end to become a senior advisor. He will continue to assist the Company on scientific and strategic matters related to the development of the CNS portfolio. Dr. Andreas Busch, Chief Innovation Officer, will effective immediately assume Dr. Currie's CSO responsibilities while Dr. Currie continues as President through year end.

**Third Quarter 2020 Financial Results**

- **Cash Position:** Cash, cash equivalents, and restricted cash balance on September 30, 2020 was approximately $71 million, as compared to approximately $61 million on June 30, 2020.

- **Research & Development Expenses:** Research and development expenses were approximately $13.7 million for the third quarter of 2020, as compared to approximately $22.3 million for the third quarter of 2019. The decrease of approximately $8.6 million was driven by a decrease of approximately $3.3 million in salaries and other employee-related expenses primarily due to lower average headcount, a decrease of approximately $2.0 million of facilities and operating costs allocated to research and development primarily from our reduced lease footprint and a decrease of approximately $3.3 million in external research costs, primarily related to the completion of praliciguat trials in the prior year.

- **General and Administrative Expenses:** General and administrative expenses were approximately $8.0 million for the third quarter of 2020, as compared to approximately $7.1 million for the third quarter of 2019. The increase was primarily due to professional fees supporting our recent financing activities, partially offset by a net decrease in employee-related and operating expenses due to lower average headcount.

- **Net Loss:** Net loss was approximately $18.8 million for the third quarter of 2020, as compared to $27.3 million for the third quarter of 2019.

**About IW-6463**

IW-6463 is the first CNS-penetrant sGC stimulator to be developed as a symptomatic and potentially disease modifying therapy for serious CNS diseases. Nitric oxide (NO) is one of several fundamental neurotransmitters, but it has yet to be leveraged for its full CNS therapeutic potential. IW-6463 stimulates sGC, a signaling enzyme that responds to the presence of NO, to enhance the body's natural ability to produce cyclic guanosine monophosphate (cGMP), an important signaling molecule. An impaired NO-sGC-cGMP signaling pathway is believed to play an important role in the pathogenesis of neurodegenerative diseases and is critical to basic neuronal functions. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

**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 is 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) 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 clinical trials; our interpretation of the data from the clinical trials; the clinical potential of our molecules; the anticipated timing of our planned clinical trials; our future business focus; the business and operations of Cyclerion; and our future financial performance and expense levels. 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 2019 Form 10-K filed on March 12, 2020, and in Cyclerion’s subsequent SEC filings, including the Form 10-Qs filed on May 4, 2020, August 3, 2020 and November 5, 2020. 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.