Cyclerion Therapeutics Announces Topline Phase 2 Results for sGC Stimulator Praliciguat in Heart Failure with Preserved Ejection Fraction (HFpEF)

October 30, 2019

*– **Study in HFpEF patients did not meet primary endpoint; company discontinuing development of praliciguat in HFpEF** –*

*– **Conference call to be held at 8:30 a.m. ET today** –*

CAMBRIDGE, Mass., Oct. 30, 2019 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company developing soluble guanylate cyclase (sGC) stimulators for the treatment of serious and orphan diseases, today announced topline results from its CAPACITY Phase 2 proof-of-concept study of praliciguat, a once-daily, orally available systemic sGC stimulator, in heart failure with preserved ejection fraction (HFpEF).

The study did not meet statistical significance on its primary endpoint of improved exercise capacity from baseline as compared to placebo, measured by cardiopulmonary exercise testing (CPET). There was clear evidence of drug exposure and pharmacological activity as judged by expected reductions in blood pressure. Praliciguat was generally well tolerated, and the safety profile supported investigation of praliciguat in other indications. While there were no trends observed in improving HFpEF symptoms, a positive trend in reducing HbA1c levels was observed in the subset of patients with diabetes. This is consistent with the results observed in the company's Phase 2 study of praliciguat in diabetic nephropathy, which were also reported today.

Cyclerion is discontinuing development of praliciguat in HFpEF. Full results from the study will be presented at a future medical meeting.

“CAPACITY-HFpEF had an innovative design, focused on those patients we believed were more likely to respond to therapy. While we are disappointed with the study results, particularly given the unmet need in HFpEF, we are very grateful to the patients who participated, as well as the physicians, other study staff and our internal teams who ran a high-quality trial that enabled us to arrive at a clear result for this indication,” said Chris Wright, M.D., Ph.D., chief medical officer at Cyclerion.

With its praliciguat Phase 2 studies completed, Cyclerion intends to focus its investments on near-term value-creation opportunities – including out-licensing praliciguat for diabetic nephropathy, advancing its STRONG SCD Phase 2 study of olinciguat in sickle cell disease, its Phase 1 study of IW-6463 for central nervous system disorders, as well as ongoing innovation – and to reduce its monthly cash expenses by 25%. As of September 30, 2019, Cyclerion had approximately $125 million of cash, cash equivalents and restricted cash. Cyclerion anticipates that this cash will be sufficient to fund its operations through Q1 2021.

About Praliciguat Phase 2 Study in HFpEF (CAPACITY)
The CAPACITY study, a randomized, placebo-controlled Phase 2 study, evaluated the safety and efficacy of once-daily praliciguat 40 mg or placebo in 196 patients with HFpEF over a 12-week period. Participating patients were 45 years or older and had HFpEF with an ejection fracture greater than or equal to 40%. The primary measure of efficacy was change in exercise tolerance, as assessed by cardiopulmonary exercise testing (CPET). No statistically significant effects were observed.

Praliciguat was generally well tolerated in this study. The most common adverse events (AEs) reported in patients treated with praliciguat in this study were headache, dizziness, urinary tract infection and hypotension. The frequency of AEs and serious AEs were similar between the treatment and placebo groups. Discontinuations due to AEs were 4.8% of praliciguat-treated patients compared to 3.3% of placebo-treated patients.

Conference Call Information
Cyclerion will host a conference call and live audio webcast today at 8:30 a.m. Eastern Time to discuss the topline results from the Phase 2 proof-of-concept studies of praliciguat. To access the conference call, please dial (800) 360-8162 (U.S. and Canada) or (409) 937-8760 (international) and reference the conference ID number 5966274. To join the live webcast, please visit the “Investors and Media” section of the Cyclerion website at www.cyclerion.com, or access it directly via the registration link, at least 15 minutes prior to the start of the call.

The call will be available for replay via telephone starting October 30, 2019 at approximately 11:30 a.m. Eastern Time, running through 10:30 a.m. Eastern Time on November 6, 2019. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) and reference the conference ID number 5966274. A webcast replay will be available on the Cyclerion website beginning approximately two hours after the event and will be archived for 21 days.

About Cyclerion Therapeutics
Cyclerion Therapeutics is a clinical-stage biopharmaceutical company harnessing the power of soluble guanylate cyclase (sGC) pharmacology to discover, develop and commercialize breakthrough treatments for serious and orphan diseases. Cyclerion is advancing its portfolio of differentiated sGC stimulator programs with distinct pharmacologic and biodistribution properties that are uniquely designed to target tissues of greatest relevance to the diseases they are intended to treat. These programs include olinciguat in Phase 2 development for sickle cell disease, IW-6463 in Phase 1 development for serious and orphan central nervous system diseases, and two preclinical programs targeting serious liver and lung diseases, respectively.

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 our intentions to out-license praliciguat and advance our clinical trials; the progression of our discovery programs into clinical development; our business and operations; ; and our sufficiency of cash. 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 those related to the possibility that we may not achieve the expected benefits of the separation from Ironwood, and that this separation could harm our business, results of operations and financial condition; the risk that we may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company; the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates; the risk of a delay in the enrollment of patients in our clinical studies; the risk that any one or more of our product candidates will not be successfully developed, approved or commercialized; our lack of independent operating history and the risk that our accounting and other management systems may not be prepared to meet the financial reporting and other requirements of operating as an independent public company; the risk that the separation from Ironwood may adversely impact our ability to attract or retain key personnel; our risk that our estimates regarding our use of cash may prove inaccurate; and the other risks and uncertainties listed under the “Risk Factors” section and elsewhere in our Registration Statement on Form S-1 filed on April 18, 2019, with the Securities and Exchange Commission (SEC), and in subsequent reports that we file with the SEC, including our Quarterly Report on Form 10-Q filed with the SEC on August 12, 2019. 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 we undertake no obligation to update these forward-looking statements, except as required by law.

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Source: Cyclerion Therapeutics, Inc.