Cyclerion Therapeutics and Collaborators to Present New Research on the Sickle Cell Disease Patient Journey at Upcoming Medical Meetings

October 8, 2019

Cyclerion will also provide an overview of its ongoing Phase 2 STRONG SCD clinical study and preclinical data supporting the investigation of olinciguat in sickle cell disease

CAMBRIDGE, Mass., Oct. 08, 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 upcoming medical meeting presentations highlighting its commitment to sickle cell disease patients and supporting its therapeutic approach to treating the disease through sGC stimulation. Cyclerion will present at the Annual National Convention of the Sickle Cell Disease Association of America (SCDAA), held October 9-12 in Baltimore, and at the Annual Sickle Cell Disease and Thalassaemia Conference (ASCAT), held October 21-23 in London.

Cyclerion and its collaborators will present new research from a sickle cell disease patient journey project. This project was designed to improve understanding and characterization of common patient experiences from birth onward, including: initial diagnosis; first crisis and emergency room experiences; transition from pediatric to adult care; navigating personal milestones such as relationships, having children, and work responsibilities; and daily management of sickle cell disease. The research project was developed by a steering committee consisting of adult patients, caregivers of pediatric patients, and healthcare providers.

“Understanding the experiences and very real challenges individuals living with sickle cell disease face is critical. This information is crucial to our collective ability to develop new treatments and care plans that have a positive impact on their lives,” said Biree Andemariam, MD, hematologist and founding director of the New England Sickle Cell Institute (NESCI) at the University of Connecticut Health Center, Chief Medical Officer at SCDAA, and a member of the patient journey steering committee. “There is a profound lack of aggregated information in the U.S. and therefore a significant need for research on the patient and caregiver journey through our complex healthcare ecosystem.”

“As we strive to develop meaningful treatments for people with serious diseases, Cyclerion is committed to understanding which symptoms are most impactful to patients’ lives,” said Chris Wright, MD, PhD, Chief Medical Officer of Cyclerion. “The patient journey research is important for broadly understanding the needs of the sickle cell disease community and for identifying new opportunities to enhance sickle cell disease care.”

In addition to the patient journey research, Cyclerion will present preclinical data on its investigational sGC stimulator olinciguat and an overview of its Phase 2 STRONG SCD study.

Cyclerion is focused on unlocking the full therapeutic potential of the nitric oxide-cyclic guanosine monophosphate (cGMP) signaling pathway, a clinically validated pathway with potential for therapeutic applications in a wide range of cardiovascular, metabolic, inflammatory, fibrotic and neurological diseases. sGC is a key node in this pathway, and Cyclerion’s targeted sGC stimulators are designed to enhance pathway signaling in the tissues of greatest relevance to the diseases each is intended to treat. Olinciguat is Cyclerion’s investigational sGC stimulator designed to target the vasculature as well as organs with high blood flow, such as the kidney and lungs, which may make it well suited for the potential treatment of sickle cell disease.

Cyclerion’s Upcoming Sickle Cell Disease Presentations :

Annual National Convention of the Sickle Cell Disease Association of America (SCDAA) – October 9-12, 2019, Renaissance Baltimore Harborplace Hotel

Oral Presentations:

- Cyclerion will present a brief overview of olinciguat, its investigational treatment for sickle cell disease, and the ongoing Phase 2 STRONG SCD study.
    - Title: Olinciguat in Development for Sickle Cell Disease
    - Presenter: Chris Wright, MD, PhD, Chief Medical Officer, Cyclerion
    - Saturday, October 12, 9:30-9:45 a.m. EDT
    - Location: Maryland DEF Ballroom

- Cassandra Trimnell, patient advocate and a member of the patient journey steering committee, will present key findings from the patient journey project, with an emphasis on pivotal milestones experienced by sickle cell patients throughout their life span.
    - Title: The Sickle Cell Disease Adult Patient Experience: The Milestones that Map the Emotional Journey
    - Presenter: Cassandra Trimnell, Founder and Executive Director of Sickle Cell 101
    - Friday, October 11, 2:45-3:00 p.m. EDT
    - Location: Baltimore B Ballroom

Sponsored Lunch:

- Cyclerion has organized a luncheon conversation, moderated by collaborators Dr. Biree Andemariam and Cassandra Trimnell, to discuss challenges faced by patients when enrolling or participating in clinical trials and how these challenges can be addressed.
    - Title: Community Voice: How Do I know if a Clinical Trial is Right for Me or My Child?
    - Moderators:
        - Biree Andemariam, MD, hematologist and Founding Director of the New England Sickle Cell Institute (NESCI) at the University of Connecticut Health Center; Chief Medical Officer, Sickle Cell Disease Association of America
        - Cassandra Trimnell, Founder and Executive Director of Sickle Cell 101
    - Saturday, October 12, 1:15-2:15 p.m. EDT
    - Location: Maryland Ballroom

Annual Sickle Cell Disease and Thalassaemia Conference (ASCAT) – October 21-23, 2019, Westminster Bridge – County Hall, London

Poster Presentations:

- Cyclerion and collaborators will present findings from the patient journey project, including metrics on emergency room visits, hospital admissions, pain crises, and missed days of school/work and a characterization of ten major pivotal

milestones that form the basis of the emotional journey for patients living with sickle cell disease.

- Title: The Emotional Journey of American Patients Living with Sickle Cell Disease
- Presenters:
  - Biree Andemariam, MD, hematologist and Founding Director of the New England Sickle Cell Institute (NESCI) at the University of Connecticut Health Center; Chief Medical Officer, Sickle Cell Disease Association of America
  - Regina Graul, Olinciguat Program Leader, Cyclerion
- Monday, October 21, 5:55-7:00 p.m. BST

- Cyclerion and collaborators will present on findings about major thematic disconnects among patients, caregivers, and healthcare providers, including discrepancies in characterizations of pain, approaches to treatment, and perceptions of quality of care.
  - Title: A Qualitative Study of Sickle Cell Patients, Caregivers and Healthcare Providers Highlighting Disconnects in Clinical Management
  - Presenters:
    - Biree Andemariam, MD, hematologist and Founding Director of the New England Sickle Cell Institute (NESCI) at the University of Connecticut Health Center; Chief Medical Officer, Sickle Cell Disease Association of America
    - Regina Graul, Olinciguat Program Leader, Cyclerion
  - Monday, October 21, 5:55-7:00 p.m. BST

- Cyclerion will present preclinical research demonstrating that its investigational sGC stimulator olinciguat was associated with improved blood flow and reduced inflammatory response caused by interactions between leukocytes and endothelial cells in a model of sickle cell disease vaso-occlusive crisis.
  - Title: Evaluation of the Soluble Guanylate Cyclase Stimulator Olinciguat in a Mouse Model of Sickle Cell Vaso-occlusive Crisis
  - Presenter: Boris Tchernychev, Principal Investigator, Cyclerion
  - Monday, October 21, 5:55-7:00 p.m. BST

About Olinciguat

Olinciguat is an investigational, orally administered, once-daily, vascular sGC stimulator designed for the potential treatment of sickle cell disease (SCD). SCD is an inherited red blood cell disorder that causes red blood cells to deform into a sickle shape, impacting blood flow to organs and tissues. These sickled red blood cells are more susceptible to hemolysis (rupturing). Upon red blood cell rupturing, nitric oxide is depleted due to arginase release and hemoglobin scavenging. Nitric oxide is an important regulator of blood flow, and the resulting deficiency of nitric oxide is believed to contribute to symptoms of SCD.

As sGC is a key node in the nitric oxide signaling pathway, olinciguat has the potential to address key symptoms and complications of SCD by addressing the disease's underlying nitric oxide deficiency. The distribution of olinciguat to the vasculature as well as to organs with high blood flow, such as the kidney and lungs, may make it well suited for the potential treatment of SCD.

Olinciguat has been granted Orphan Drug Designation for SCD by the U.S. Food and Drug Administration and is currently in a Phase 2 study in patients with SCD, the STRONG SCD study.

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 five 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, praliciguat in Phase 2 trials for heart failure with preserved ejection fraction (HFpEF) and for diabetic nephropathy, 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. 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 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, including olinciguat; the risk of a delay in the enrollment of patients in our clinical studies, including the STRONG SCD study; 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; 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. 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.