UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **JANUARY 13, 2020**

CYCLERION THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Massachusetts	**001-38787**	**83-1895370**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

301 Binney Street
Cambridge, Massachusetts 02142
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(857) 327-8778**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, no par value	CYCN	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On January 13, 2020, the Cyclerion Therapeutics, Inc. ("Cyclerion" or the "Company") issued a press release announcing positive Phase 1 study results that provide the foundation for continued development of IW-6463, an oral, once-daily central nervous system (CNS)-penetrant soluble guanylate cyclase (sGC) stimulator for the treatment of serious neurodegenerative diseases. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Current Report on Form 8-K.

Cyclerion management will discuss IW-6463 and its CNS program, along with its diabetic nephropathy and sickle cell clinical programs, at the J.P. Morgan Healthcare Conference on Wednesday January 15, 2020. The presentation will be live webcast at 9:00AM PST (12:00PM EST). A copy of the presentation is attached hereto as Exhibit 99.2 and is incorporated by reference into this Current Report on Form 8-K. The presentation will be followed by a question and answer session to be held at 9:30AM PT (12:30PM EST).

A live webcast of the presentation can be accessed at https://jpmorgan.metameetings.net/events/hc20/sessions/29869-cyclerion/webcast and a live webcast of the question and answer session can be accessed at https://jpmorgan .metameetings.net/events/hc20/sessions/30203-cyclerion-q-a/webcast. The presentation materials and replays of the webcast and the question and answer sessions will be available for 90 days following the conference on the "Investors & Media" page of the Company's website at https://ir.cyclerion.com/news-events/news-releases.

This report and the webcasts may contain 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 anticipated timing of release of topline results of our clinical trials; the progression of our discovery programs into clinical development; 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. Applicable risks and uncertainties include but are not limited to statements about possible or assumed future results of operations; preclinical, clinical and non-clinical studies, the interpretation of data therefrom and the ability to replicate findings from such studies; business strategies, research and development plans, collaborations, partnerships, out-licensing (including without limitation with respect to praliciguat), regulatory activities and any timing thereof; competitive position, potential growth or commercial opportunities; the clinical potential, application, commercialization or potential markets of or for any proposed products; the anticipated timing of release of data from any clinical trials; our ability to obtain necessary approvals from regulatory authorities; our ability to advance product candidates in clinical trials; that regulatory approval processes are lengthy, time-consuming and inherently unpredictable; that significant variability in safety or efficacy may appear in different clinical studies of the same product candidate; that product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite promising preclinical testing and earlier clinical studies; the timing, investment and associated activities involved in developing and obtaining regulatory approval for our product candidates; our plans with respect to the development of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies; the efficacy of our product candidates; and the risks more fully listed under the heading "Risk Factors" and elsewhere in our Registration Statement on Form S-1 filed on April 18, 2019, and in Cyclerion's subsequent SEC filings, including the Form 10-Q filed on November 12, 2019. Investors are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements (except as otherwise noted) would speak only as of the respective dates of this report and the webcasts, and Cyclerion undertakes no obligation to update these forward-looking statements, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description
99.1	Press Release of Cyclerion Therapeutics, Inc. dated January 13, 2020
99.2	Investor Presentation of Cyclerion Therapeutics, Inc. dated January 13, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cyclerion Therapeutics, Inc.

Dated: January 13, 2020

By: /s/ William Huyett
Name: William Huyett
Title: Chief Financial Officer

FOR IMMEDIATE RELEASE

Cyclerion announces IW-6463 phase 1 healthy volunteer study results that support further development for neurodegenerative diseases

– Results in 110 subjects demonstrate favorable safety, CNS pharmacokinetics, and evidence of target engagement –

– Study underway in elderly subjects to further assess cerebral blood flow and additional translational measures of CNS target engagement; topline readout anticipated in mid-2020 –

– Company will present, with webcast, at the J.P. Morgan Healthcare Conference on Wednesday, January 15, 2020 at 9AM PST (noon EST) –

CAMBRIDGE, Mass., Jan. 13, 2020 — Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), today announces positive Phase 1 study results that provide the foundation for continued development of IW-6463, an oral, once-daily central nervous system (CNS)-penetrant soluble guanylate cyclase (sGC) stimulator for the treatment of serious neurodegenerative diseases. The nitric oxide pathway and sGC stimulation have long been known to be a central physiological regulator in the central nervous system, impacting cerebrovascular blood flow, neuroinflammation, neuronal function and metabolism.

“Our Phase 1 healthy volunteer study results indicate that IW-6463 was well tolerated. Pharmacokinetic (PK) data, obtained from both blood and cerebral spinal fluid (CSF), support once-daily dosing with or without food and demonstrate IW-6463 penetration across the blood-brain-barrier at levels expected to be pharmacologically active. We are excited about the therapeutic possibilities for IW-6463 as a first-in-class, brain penetrant sGC stimulator,” said Chris Wright, M.D., Chief Medical Officer of Cyclerion. “These results, together with our preclinical data, provide strong support for continued development of IW-6463 as a potential new medicine for serious neurodegenerative diseases.”

Phase 1 Study Design and Topline Results

The company’s first IW-6463 Phase 1 study was conducted in 110 healthy volunteers aged 18-63 years to evaluate safety and pharmacokinetics in blood and CSF. The three-stage study evaluated: a) single ascending doses, b) multiple ascending doses (over 14 days) and c) food interaction effects. Study results demonstrated that IW-6463 was well tolerated across the tested dose levels. The most common adverse events (AEs) observed in the active treatment group were headache, nausea, dizziness, somnolence and fatigue. All AEs were mild and no serious adverse events (SAEs) were observed. IW-6463 administration resulted in a mild reduction in blood pressure, a known characteristic of sGC stimulators, providing evidence of peripheral pharmacological activity and target engagement. PK data obtained from the CSF demonstrate penetration of IW-6463 into the CNS at levels expected to be pharmacologically active. Food interaction results indicate that IW-6463 may be taken with or without food. These data, together with plasma PK results, support development of IW-6463 as a once-daily orally administered therapeutic.

Ongoing and Planned Development Activities

A translational pharmacology study in approximately 24 elderly subjects is ongoing. This study will evaluate safety, PK, and measures of CNS pharmacological activity, including cerebral blood flow by MRI and additional translational measures. Topline study results are expected in mid-2020. These results are intended to enable Cyclerion to direct further development in high-value CNS indications where biological and genetic data suggest an important role for nitric oxide and cyclic guanosine monophosphate (cGMP) signaling.

Presentation at J.P. Morgan Healthcare Conference

Cyclerion will discuss IW-6463 and its CNS program, along with its diabetic nephropathy and sickle cell disease clinical programs, at the J.P. Morgan Healthcare Conference on Wednesday, January 15, 2020. The presentation will be webcast at 9:00AM PST (12:00PM EST). Note that the webcast presentation EST time was incorrect on the company's December 23, 2019 webcast press release announcement, and the correct time is 12:00PM EST.

The presentation will be followed by a question and answer session to be held at 9:30AM PT (12:30PM EST). A live webcast of the presentation and the Q&A session can be accessed on the following links:

Presentation link: https://jpmorgan.metameetings.net/events/hc20/sessions/29869-cyclerion/webcast

Q&A link: https://jpmorgan.metameetings.net/events/hc20/sessions/30203-cyclerion-q-a/webcast

A replay of the presentation will be posted on the Cyclerion website following the event.

About IW-6463

IW-6463, a CNS-penetrant sGC stimulator, is being developed as a potentially disease modifying therapy for neurodegenerative diseases. Nitric oxide is one of several fundamental neurotransmitters, one that has yet to be leveraged for its therapeutic potential in the CNS. sGC stimulators work synergistically with the nitric oxide naturally produced in the body to boost the positive effects of nitric oxide, even when the body is not producing enough. There are clear links between nitric oxide signaling defects and neurodegenerative diseases. Evidence indicates that endothelial cell loss and nitric oxide dysregulation are contributors to neurodegenerative diseases and result in reduced blood flow, vascular leakage, inflammation, and neuronal dysfunction/loss. sGC is expressed widely throughout the CNS and CNS vasculature. In preclinical studies, IW-6463 has been associated with increased cerebral blood flow, reduced markers of neuroinflammation, improved neuronal health, neuroprotective effects and enhanced cellular bioenergetics and mitochondrial function.

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 praliciguat which recently completed Phase 2 studies and which the company intends to out-license for further development in diabetic nephropathy, olinciguat in Phase 2 development for sickle cell disease, IW-6463 in Phase 1 development for serious CNS 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 the anticipated timing of release of topline results of our clinical trials; the progression of our discovery programs into clinical development; 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. Applicable risks and uncertainties include those related to our ability to obtain necessary approvals from regulatory authorities; our ability to advance product candidates in clinical trials; that regulatory approval processes are lengthy, time-consuming and inherently unpredictable; that significant variability in safety or efficacy may appear in different clinical studies of the same product candidate; that product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite promising preclinical testing and earlier clinical studies; the timing, investment and associated activities involved in developing and obtaining regulatory approval for our product candidates; our plans with respect to the development of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies; the efficacy of our product candidates; and the risks more fully listed under the heading “Risk Factors” and elsewhere in our Registration Statement on Form 10 filed on March 11, 2019, and in Cyclerion’s subsequent SEC filings, including the Form 10-Q filed on November 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 Cyclerion undertakes no obligation to update these forward-looking statements, except as required by law.

Contact

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

Exhibit 99.2


cyclerion
J.P. Morgan Healthcare Conference
January 13, 2020
Peter Hecht, CEO

Safe Harbor Statement

This presentation contains forward-looking statements. Any statements contained in this presentation that are not historical facts may be deemed to be forward looking statements. Words such as "anticipate," "believe," "potential," "expect," "may," "will," "should," "could," "plan," "estimate," "target," "project," "contemplate," "intend," "future," "will," "predict," "continue," and the negative of these terms and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Cyclerion's current expectations, projections and trends, are only predictions and involve known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Investors are cautioned not to place undue reliance on these forward-looking statements, which include but are not limited to statements about possible or assumed future results of operations; preclinical, clinical and non-clinical studies, the interpretation of data therefrom and the ability to replicate findings from such studies; business strategies, research and development plans, collaborations, partnerships, out-licensing (including without limitation with respect to praliciguat), regulatory activities and any timing thereof; competitive position, potential growth or commercial opportunities; the clinical potential, application, commercialization or potential markets of or for any proposed products; the anticipated timing of release of data from any clinical trials; and the size and design of those clinical trials. Applicable risks and uncertainties include those listed under the heading "Risk Factors" and elsewhere in our Registration Statement on Form S-1 filed with the Securities and Exchange Commission (SEC) on April 18, 2019, and in our subsequent SEC filings, including our Quarterly Report on Form 10-Q filed with the SEC on August 12, 2019. These forward-looking statements speak only as of the date of this presentation, and we undertake no obligation and do not intend to update these forward-looking statements.

Priorities for 2020

sGC

1 **DN praliciguat partnering:**

out-license discussions based on promising phase 2

2 **SCD olinciguat phase 2 completion:**

potential for raising standard of care across four therapeutic domains

3 **CNS IW-6463 advancement:**

advancement from successful phase 1 in healthy volunteers to ongoing study in elderly subjects

1 Praliciguat in diabetic nephropathy (DN): out-license discussions based on promising phase 2

Data support further development > **Out-license discussions underway**

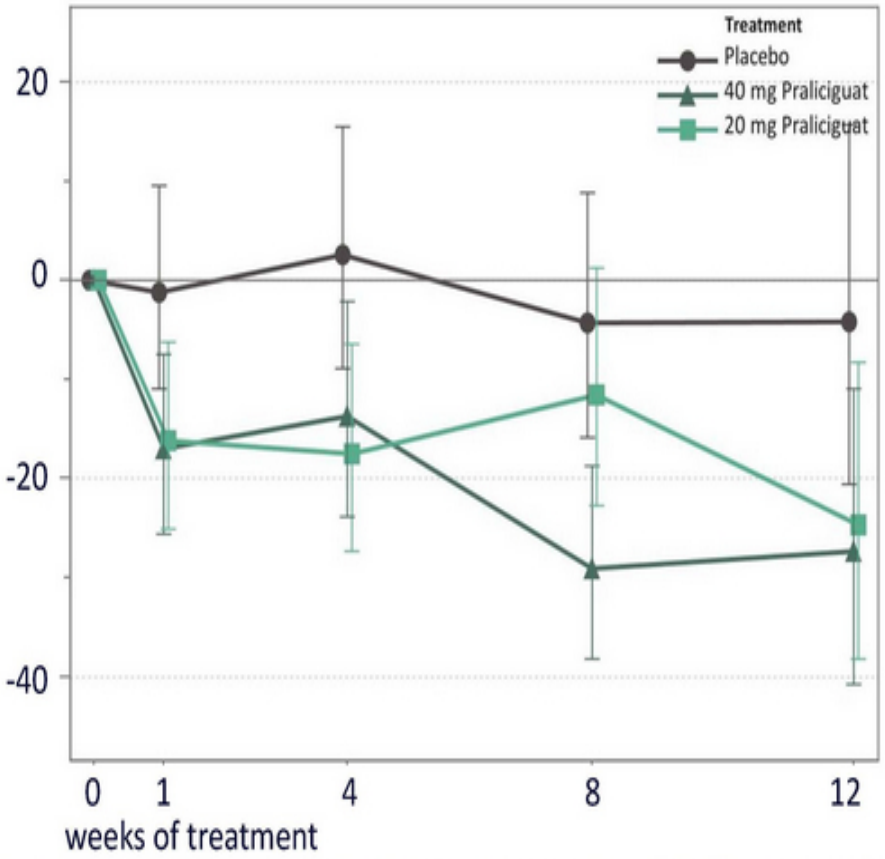
- UACR reductions on top of standard of care
  - 20%[1] placebo-adjusted (p=0.0303[2])
  - 24%[1] absolute change from baseline
- reductions in blood pressure, HbA1c, total and LDL cholesterol
- favorable safety profile, consistent with previous studies
- attractive dosing and PK relative to others in class

1. Modified intent-to-treat population, pooled praliciguat 20 and 40mg dose, placebo-adjusted average of weeks 8 and 12 (primary endpoint)
2. Nominal p-value; not adjusted for multiplicity

Phase 2 showed promising improvement in UACR

% UACR change from baseline

LS mean (90% CI) change UACR in (mg/g) (mITT)[1]



(90 % CIs by dose & timepoint)

1. mITT: modified intent-to-treat population n=133 excludes data from site 00A where data inconsistencies were observed in both the treatment and control groups

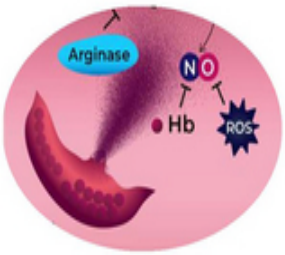
2 Olinciguat in sickle cell disease (SCD): potential for raising standard of care across four therapeutic domains

Dynamic mechanism - alone or complementing approved treatments > **Topline phase 2 results mid-2020**

- upstream + downstream pharmacological intervention
- impact potential in four clinical domains: anemia, daily symptoms, VOC, and organ protection--not fully addressed by approved therapies
- oral, QD drug for use in a broad range of SCD patients
- STRONG SCD trial designed to assess safety and pharmacodynamic effects across full dose range

Olinciguat: upstream and downstream intervention in SCD

Increased hemolysis leads to reduced nitric oxide state



sGC restores deficient nitric oxide signaling

Upstream

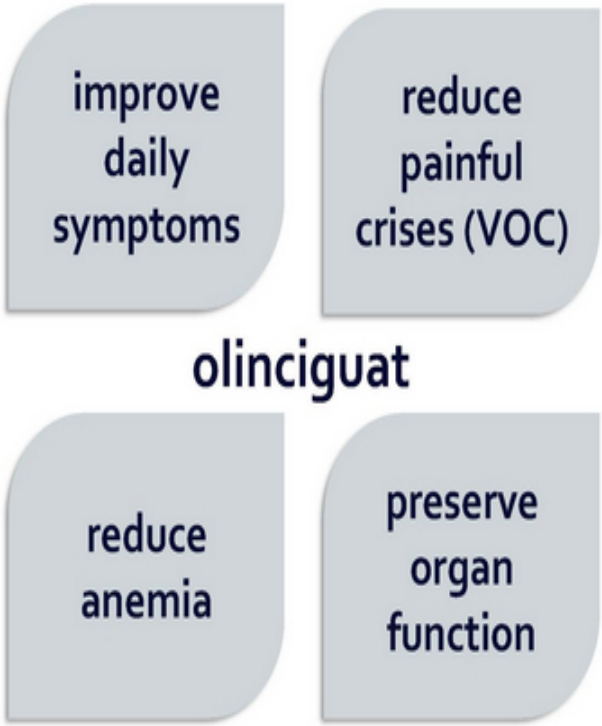
- increased HbF leads to reduced proportion of sickled RBCs1

Downstream

- improved blood flow
- decreased vascular inflammation & cell adhesion
- improved endothelial integrity

1. Conran, N., & Torres, L. (2019). cGMP modulation therapeutics for sickle cell disease. *Experimental Biology and Medicine*, 244(2), 132–146.

Potential to raise standard of care across four therapeutic domains



- newly approved therapies each target a single clinical domain…
- …olinciguat has the potential to improve four
- daily symptoms and end-organ protection remain unaddressed, decreasing QoL and increasing mortality
- further improvement in anemia and/or VOC possible with olinciguat alone or as add-on therapy serving broad SCD patient population

STRONG SCD

Olinciguat phase 2 trial designed to support rapid advancement

Topline results expected mid-2020

DESIGN

- double blind
- global sites
- 4 dose levels
- up to 88 patients aged 16 – 70
- 12-week treatment in all SCD genotypes

OBJECTIVES

- assess safety and tolerability
- confirm PK profile in SCD patients
- development of the CYCN fit-for-purpose patient-reported outcomes (ePRO) instrument
- signs of pharmacodynamic effect: biomarkers (Hb, HbF, inflammation, adhesion) and daily symptom effects

INSIGHTS FOR PHASE 3 DESIGN

- endpoint selection based on results (biomarkers and ePRO)
- determine study sample size and dose(s)

3 IW-6463 in CNS: advancing development for treatment of serious neurodegenerative diseases

Ph 1 showed safety, target engagement, CNS exposure → **Additional clinical studies in 2020 to accelerate and de-risk program**

Preclinical evidence: stimulation of nitric oxide-cGMP pathway improves determinants of brain health

Impaired brain function associated with low nitric oxide-cGMP

Enhanced NO-cGMP in the CNS leads to:

- enhanced neuronal function
- increased cerebral vascular function
- decreased microglial activity
- improved mitochondrial output

Potential for improved brain health

1. Cyclerion's pre-clinical work www.cyclerion.com

IW-6463 potential to restore nitric oxide-cGMP signaling

Nitric oxide insufficiency leads to

- neuroinflammation and neurodegeneration
- impaired neurovascular blood flow

Improved brain health

- decreased inflammation
- increase blood flow
- neuroprotection and enhanced cognition

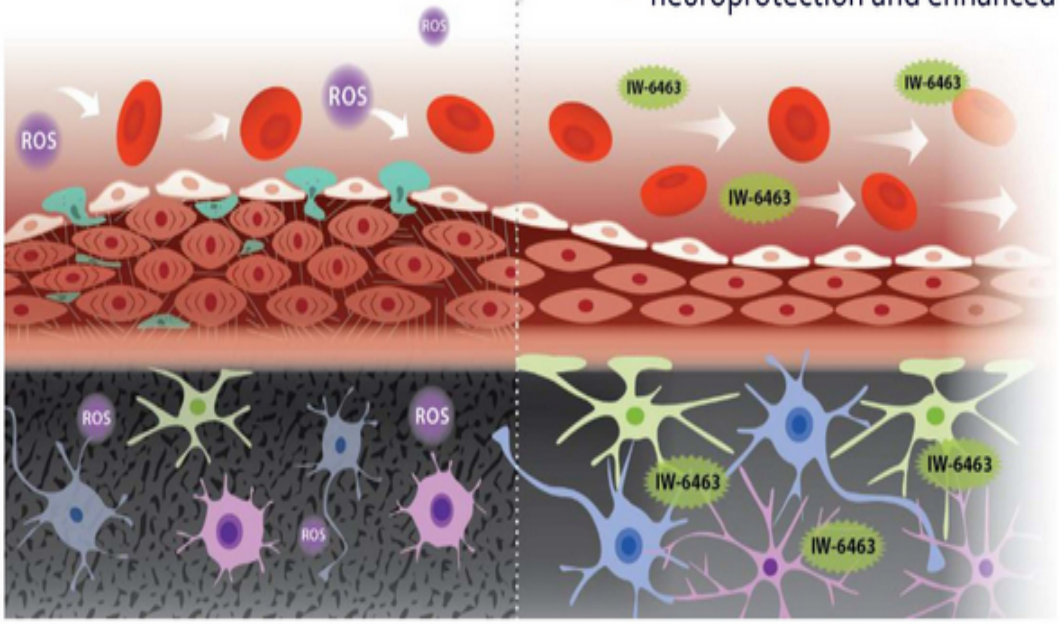


Figure adapted from Tobin, Zimmer et al. J Pharmacol Exp Ther 2018;365:664-675. Copyright © 2018 The Author(s).

Positive phase 1 IW-6463 results support further development

Newly released—completed December 2019

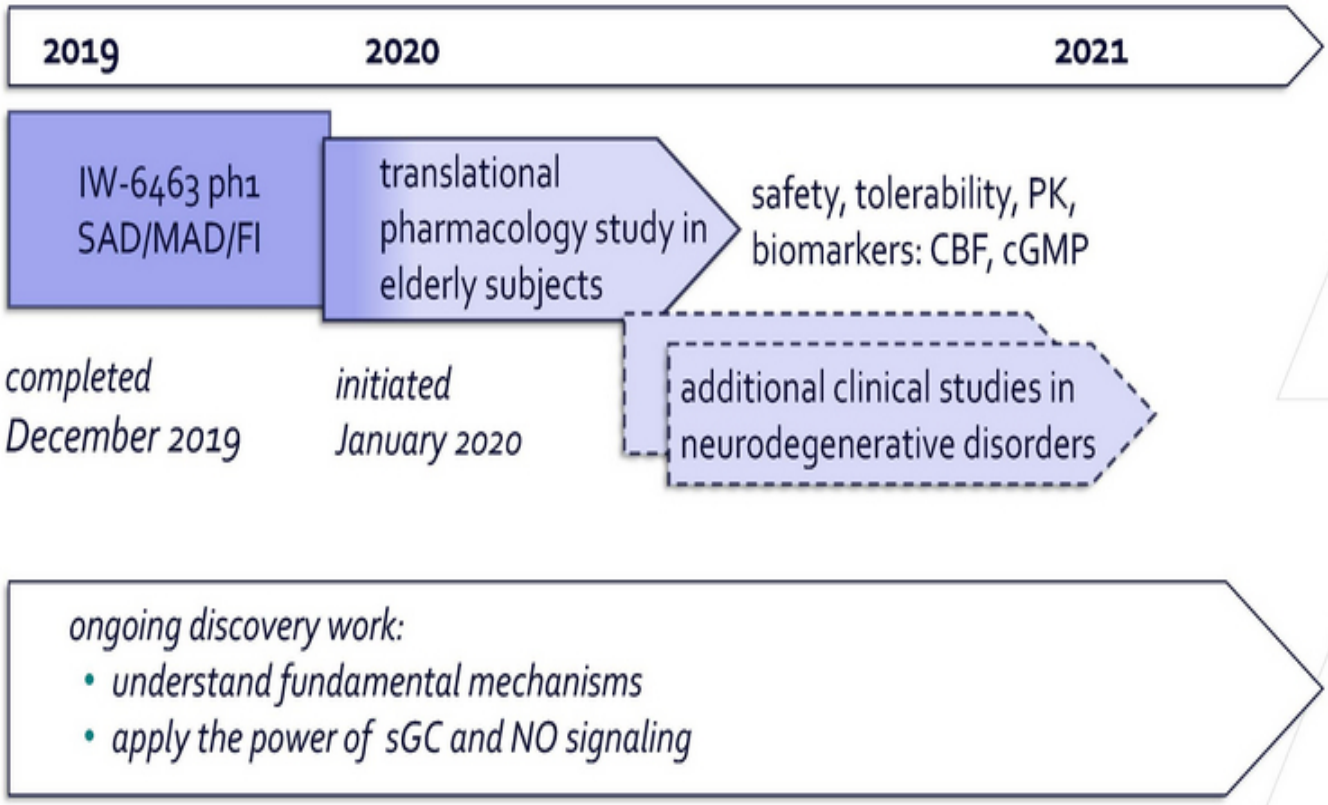
Phase 1 study design

- 3 stage: SAD, MAD and food interaction
- 110 healthy volunteers
- age range 18-63
- assessed safety, PK (blood & CSF)
- wide dose / exposure range tested

Insights

- CNS drug presence at levels expected to be pharmacologically active
- QD dosing, linear and predictable PK
- may be taken with or without food
- evidence of target engagement (blood pressure)
- well-tolerated at all dose levels
- all AEs mild in severity, no SAEs

Clinical direction: accelerate and de-risk into high value CNS indications



Cyclerion

- 2020 catalysts across programs
  - partnering
  - clinical trials
- ~$102M cash[1] and reduced burn support our priorities into Q2 2021
- Team, talent and intensity to deliver

1. Preliminary, unaudited unrestricted cash, cash equivalents and restricted cash balance as of Dec 31, 2019

Priorities for 2020

sGC

1 **DN praliciguat partnering:**

out-license discussions based on promising phase 2

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