A PHASE 3, OPEN-LABEL EXTENSION OF COURAGE-ALS (CY 5031)

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To assess the long-term safety and tolerability of reldesemtiv in patients with ALS

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON53955

Source
ToetsingOnline

Brief title
CY5032

Condition

- Neuromuscular disorders

Synonym
ALS, Amyotrophic Lateral Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Cytokinetics
Source(s) of monetary or material Support: Cytokinetics Inc

Intervention

Keyword: ALS, Amyotrophic Lateral Sclerosis, reldesemtiv

Outcome measures

Primary outcome

The incidence of adverse events (AEs) in the patient population

Secondary outcome

• Time to the first occurrence of respiratory insufficiency (defined as tracheostomy for any reason or the use of non-invasive ventilation (NIV) for >=22 hours per day for >=10 consecutive days) or death from date of randomization in CY 5031 through Week 48 of CY 5032

• Time to the first hospitalization from Day 1 in CY 5031 through Week 48 of CY 5032

• Combined assessment of change in ALSFRS-R total score, time to onset of respiratory insufficiency, and survival time from baseline of CY 5031 through Week 48 of CY 5032 and from Week 24 of CY 5031 through Week 48 of CY 5032

• Changes in ALS Functional Rating Scale - Revised (ALSFRS-R) total score from baseline of CY 5031 through Week 48 of CY 5032 and from Week 24 of CY 5031 through Week 48 of CY 5032

• Slopes of the changes in ALSFRS-R total score from baseline of CY 5031 through Week 48 of CY 5032 and from Week 24 of CY 5031 through Week 48 of CY 5032

Study description

Background summary

Reldesemtiv, a fast skeletal muscle troponin activator, is being investigated as a potential therapy to slow the decline of skeletal muscle function in

patients with ALS. Patients who have completed the Phase 3 clinical trial (COURAGE-ALS [CY 5031]) of reldesemtiv in patients with ALS may continue to receive reldesemtiv in the open label extension (OLE), CY 5032. During the last 24 weeks of dosing in CY 5031, all patients receive open-label reldesemtiv; consequently, all patients eligible for and entering CY 5032 will have already demonstrated acceptable tolerance of reldesemtiv when they begin dosing. The OLE permits patients to continue to receive reldesemtiv after completion of CY 5031.

Study objective

To assess the long-term safety and tolerability of reldesemtiv in patients with ALS

Study design

Open-label Phase-3

Intervention

300 mg reldesemtiv twice daily.

Study burden and risks

2x physical examination
2x neurological examination
6x blood and urine sampling
14x questionnaire taking.

Contacts

Public
Cytokinetics

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Able to comprehend and willing to sign an Informed Consent Form (ICF). If the patient is able to comprehend, but non-written consent is given, an impartial witness must sign the ICF form
• Completed dosing in CY 5031

Exclusion criteria

• Has taken an investigational study drug (other than reldesemtiv) prior to dosing, within 30 days or five half-lives of the prior agent, whichever is greater.
When during the study the liver and/or kidney function tests rise to above 3x ULN, the medication intake will be stopped permanently.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	reldesemtiv

Ethics review

Approved WMO Date:	12-10-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-01-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-03-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-004727-33-NL
CCMO	NL81821.041.22
Other	www.clinicaltrials.gov