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

Published: 12-10-2022 Last updated: 07-04-2024

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

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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

Oyster Point Blvd 350 San Francisco CA 94080 US

#### **Scientific**

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