Revision: 2.0 dd 25SEP2024

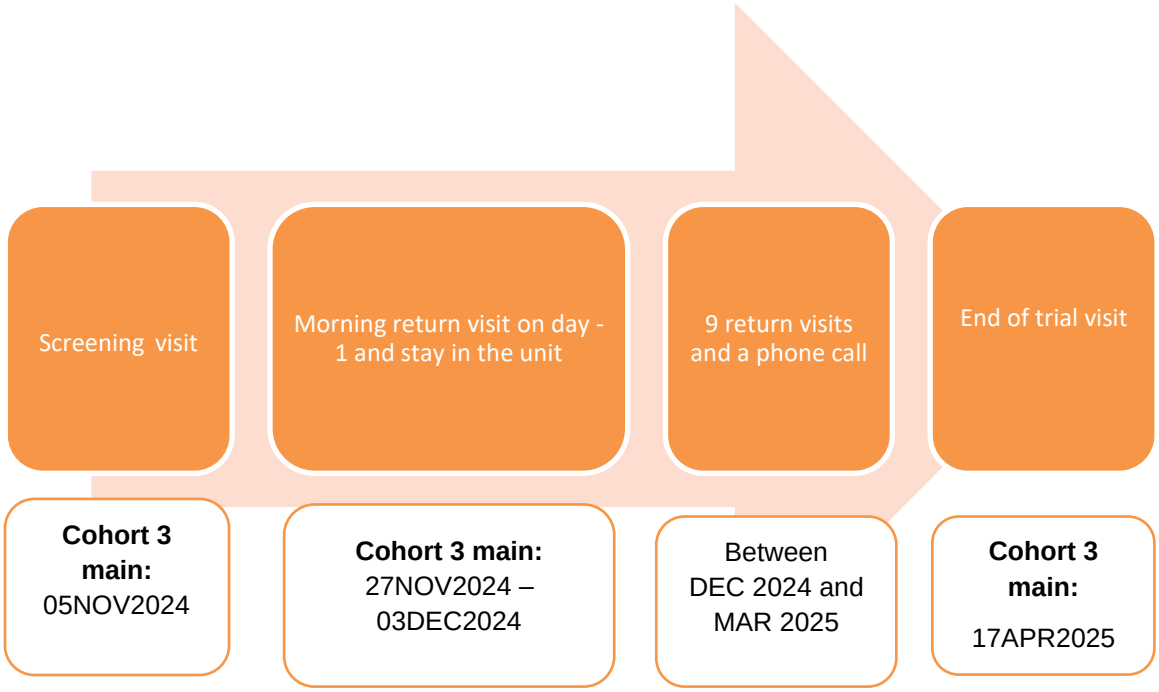
STUDY NUMBER: BE-80-2300051

STUDY FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat the nervous system disease ALS.** Are you interested in participating and giving science a boost?

We hereby would like to provide you with an overview of the study: duration of **± 6 months**.



Study BE-80-2300051 will be conducted in 8 **study cohorts with 8 participants per cohort.** In each cohort, 2 volunteers (the sentinel group) will receive the medication a few days before the rest of the group (the main group). This information sheet only contains information about Cohort 3. In this cohort, the medication is administered subcutaneously (under the skin). If interested, you can let us know your preferred cohort. Ultimately, you can only participate in one cohort. More details can be found further in this information sheet.

Selected as a reserve? You enter the unit with the possibility of stepping in as an effective participant in case someone drops out last minute. You are available for all study dates and adhere to the study conditions. If you don't need to fill in, you can go home after the dosing of the effective participants.

INCLUSION CRITERIA

- **Last participation in other clinical trial (study medication*):**
  - **Cohort 3 main:** no later than 07AUG2024

Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.

- Healthy men and women
- Age: between 18 and 65 years (inclusive) at screening
- BMI: between 18.0 and 30.0 kg/m²
  - Weight between 50.0 and 110.0 kg
- Non-smoker or stopped smoking at least 6 months before the screening.
- You have been vaccinated for COVID-19, including 2 boosters.
- Not using any medication, vitamins, or homeopathic substances (in consultation with the physician, it may be possible to continue taking certain medications during the study)
- During the study, you will be asked to adhere to restrictions regarding physical activities.
- Contraception:
  - **Fertile women:**
    - Use of an effective contraception method (e.g., oral contraception, intra-uterine device, …) until 6 months after the administration of the study medication
  - **Infertile women:**
    - postmenopausal (no menstruation for at least 12 months)
    - **OR** hysterectomy (removal of uterus)
    - **OR** bilateral ovariectomy (removal of both ovaries)
    - **OR** bilateral salpingectomy (removal of both fallopian tubes)
  - **Men**:
    - If your female partner is fertile, you must use a double barrier method (e.g: condom + oral contraception) until 8 months after the administration of the study medication or abstinence.
    - You must refrain from donating sperm during the study until 8 months after the administration of the study medication.
- **Your profile is not eligible if you:**
  - Have donated or lost > 500 ml blood or blood products within 90 days before the first administration of the study medication.
  - Had a serious infection within 4 weeks before the first administration of the study medication.
  - Have a bleeding disease.
  - Have a skin disease (including eczema, psoriasis, vitiligo, …) or a large part of your body is covered with tattoos.
  - Use drugs or alcohol excessively (drug and alcohol tests will be performed during the study).
  - Have frequent elevations of bilirubin in your blood. This blood value will be measured at screening. A mild degree of the Gilbert syndrom is allowed.
  - Have ever been in contact or infected with tuberculosis or hepatitis B.
  - Have a history of recurrent headaches, including migraine.
  - Participated in a previous cohort of the study BE-80-2300051.
- Participation of CPU employees or Sponsor employees:
  - You are not (family of) an employee of the sponsor UCB or of SGS, who is directly involved in the study.

COURSE OF THE STUDY

Cohort 3 main		
Screening		
Tuesday 5 November 2024	Screening	Standard screening visit (fasted) +/-3h
Study		
Wednesday 27 November 2024	D-1	Morning return visit Evening admission around 18h
Thursday 28 November 2024	**D1**	**Stay in the unit:** **Administration of the study medication**
Friday 29 November 2024	D2	Stay in the unit
Saturday 30 November 2024	D3	Stay in the unit
Sunday 1 December 2024	D4	Stay in the unit
Monday 2 December 2024	D5	Stay in the unit
Tuesday 3 December 2024	D6	Leave the unit around 11h
Thursday 5 December 2024	D8	Return visit
Sunday 8 December 2024	D11	Return visit
Thursday 12 December 2024	D15	Return visit
Sunday 22 December 2024	D29	Return visit
Thursday 9 January 2025	D43	Return visit
Thursday 23 January 2025	D57	Return visit
Thursday 6 February 2025	D71	Return visit
Thursday 20 February 2025	D85	Return visit
Thursday 27 February 2025	D92	Return visit
Thursday 20 March 2025	D113	Phone call
End of Trial visit		
Thursday 17 April 2025	VD	Standard visit (+/- 3h)

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 3000** for completing the entire study (including screening visit)
- **€ 400** for reserve volunteers (including screening visit)
- **€ 50** for the screening visit

**Tax-free in Belgium.* *In addition, you will receive reimbursement for your travel expenses, which is set at € 0,3542 per km, with a maximum of 120 km (one way).*

Payment of those who are screen failures & reserves will be started after dosing. When you are an effective participant, payment will start after your final study visit. The pay-out period will take ± 4 to 6 weeks.

In case of early termination of the study, this payment can be adjusted based on the final study duration as well as based on the reason for early termination. This decision will be made jointly by the SGS study team.

INTEREST IN PARTICIPATING

Registration for this study only indicates your interest and does not obligate you to participate, nor us to include you as a participant.

Registration can now be done by emailing the requested information below to pionier@sgs.com or by calling the number **+32 (0)3 217 21 72** *(between 8h30-12h and 13h-17h)*:

Study number: BE-80-2300051
Cohort 3 main

Last name and first name: ...
Date of birth: ...
Telephone number: ...

The time of your registration determines the order of processing of your profile for this study.

We will contact you as soon as possible.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300051.

SGS CPU
Drie Eikenstraat 655
B-2650 Edegem
+32 (0)3 217 21 72
pionier@sgs.com