Revision: 2.0 dd 21OCT2024

STUDY NUMBER: BE-80-2300674 PART A

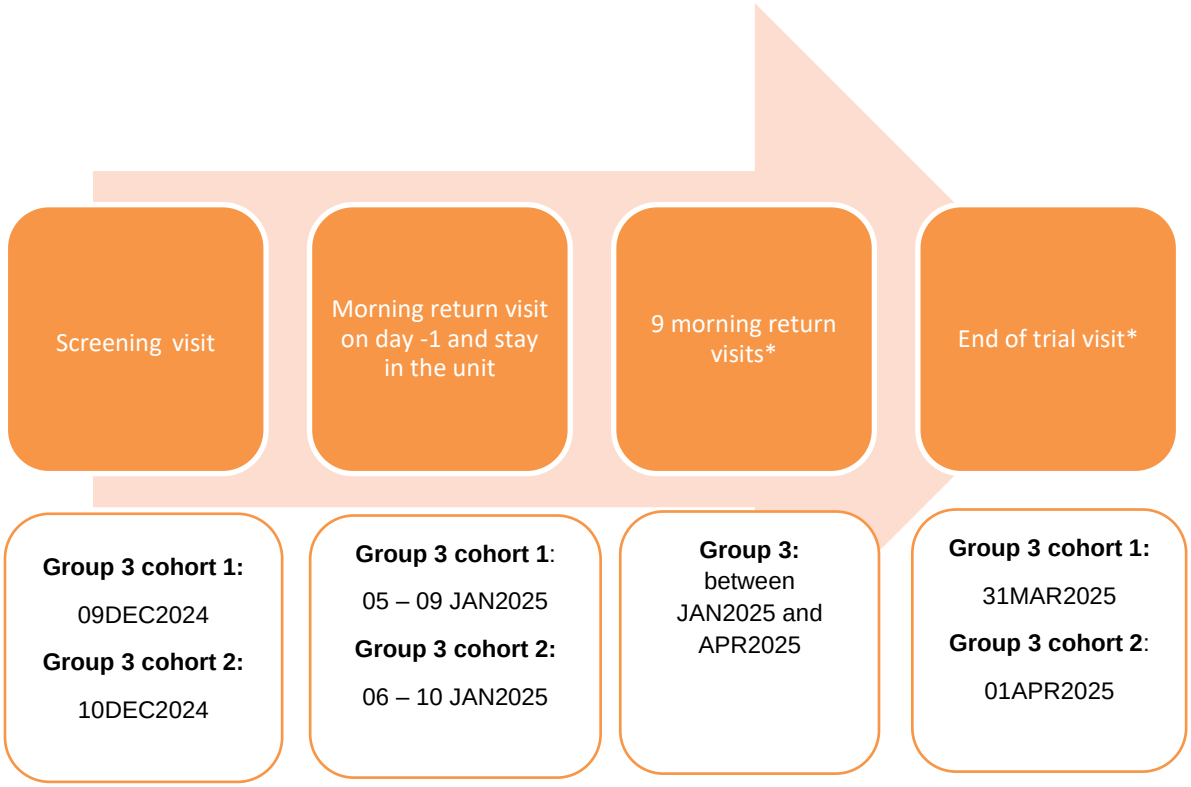
STUDY FOR THE TREATMENT OF LUNG DISEASES

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat lung diseases.**

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 **± 16 weeks**.



***The last return visit can be at the same day as the end of trial visit.

Study BE-80-2300674 part A will be conducted in 7 study groups with 8 participants per group. Each group consists of 2 cohorts. The 6 volunteers from cohort 2, are dosed at least 1 day after the 2 volunteers from cohort 1. This information sheet only contains information about group 3. In these groups, the medication is administered **intravenously** (through the vein**).** More details can be found further in this information sheet. If interested, you can let us know your preferred cohort. Ultimately, you can only participate in one cohort.

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 (last study medication*):**
  - **Group 3 cohort 1:** not later than 07NOV2024
  - **Group 3 cohort 2:** not later than 08NOV2024

  **Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men
- Age: between 18 and 60 years (inclusive)
- BMI: between 18.5 and 29.9 kg/m² (inclusive)
- Non-smoker or smoking maximum 10 cigarettes, 10 vapes, 3 pipes or 3 cigars per day.
  - Please note: nicotine containing products may not be used during your stay in the unit
- 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 and consuming alcoholic products.
- Contraception:
  - You must use a condom from day 1 until the end of trial visit.
  - You must refrain from donating sperm from day 1 until the end of trial visit
- **Your profile is not eligible if you:**
  - Had a bone fracture within 6 months prior to screening.
  - Have serious musculoskeletal complaints (arthrosis, arthritis, ….)
  - Have a history or suffer regularly of relevant orthostatic hypotension, fainting spells, or blackouts.
  - Had a major surgery within 3 months prior to screening or planned during the study.
  - Participated in a previous group of studie BE-80-2300674.

COURSE OF THE STUDY

Group 3 Cohort 1		
Screening		
Monday 9 December 2024	Screening	Standard screening visit (fasted) +/- 3h
Period1 1		
Sunday 5 January 2025	D-1	Morning return visit (fasted 10h) and evening admission around 18h
Monday 6 January 2025	**D1**	**Stay in the unit:** **Administration of the study medication**
Tuesday 7 January 2025	D2	Stay in the unit
Wednesday 8 January 2025	D3	Stay in the unit
Thursday 9 January 2025	D4	Leave the unit around 11h
Friday 10 January 2025	D5	Morning return visit
Saturday 11 January 2025	D6	Morning return visit
Monday 13 January 2025	D8	Morning return visit (fasted 10h)
Monday 20 January 2025	D15	Morning return visit (fasted 10h)
Monday 3 February 2025	D29	Morning return visit (fasted 10h)
Monday 17 February 2025	D43	Morning return visit
Monday 3 March 2025	D57	Morning return visit (fasted 10h)
Monday 17 March 2025	D71	Morning return visit
End of trial visit		
Monday 31 March 2025	EOT	Standard visit (fasted 10h) +/- 3h

Group 3 Cohort 2		
Screening		
Tuesday 10 December 2024	Screening	Standard screening visit (fasted) +/- 3h
Period 1		
Monday 6 January 2025	D-1	Morning return visit (fasted 10h) and evening admission around 18h
Tuesday 7 January 2025	**D1**	**Stay in the unit:** **Administration of the study medication**
Wednesday 8 January 2025	D2	Stay in the unit
Thursday 9 January 2025	D3	Stay in the unit
Friday 10 January 2025	D4	Leave the unit around 11h
Saturday 11 January 2025	D5	Morning return visit
Sunday 12 January 2025	D6	Morning return visit
Tuesday 14 January 2025	D8	Morning return visit (fasted 10h)
Tuesday 21 January 2025	D15	Morning return visit (fasted 10h)
Tuesday 4 February 2025	D29	Morning return visit (fasted 10h)
Tuesday 18 February 2025	D43	Morning return visit
Tuesday 4 March 2025	D57	Morning return visit (fasted 10h)
Tuesday 18 March 2025	D71	Morning return visit
End of trial visit		
Tuesday 1 April 2025	EOT	Standard visit (fasted 10h) +/- 3h

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 2300** 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 € 0,4246 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-80-2300674 Part A
Group 3 cohort 1 or cohort 2

Please clearly indicate your group **AND** cohort

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 **(between 8 a.m. and 5 p.m.)** to make an appointment for the screening visit, if you fulfill the inclusion criteria.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300674.

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