Revision: 2.0 dd 23OCT2024

STUDY NUMBER: BE-80-2300237

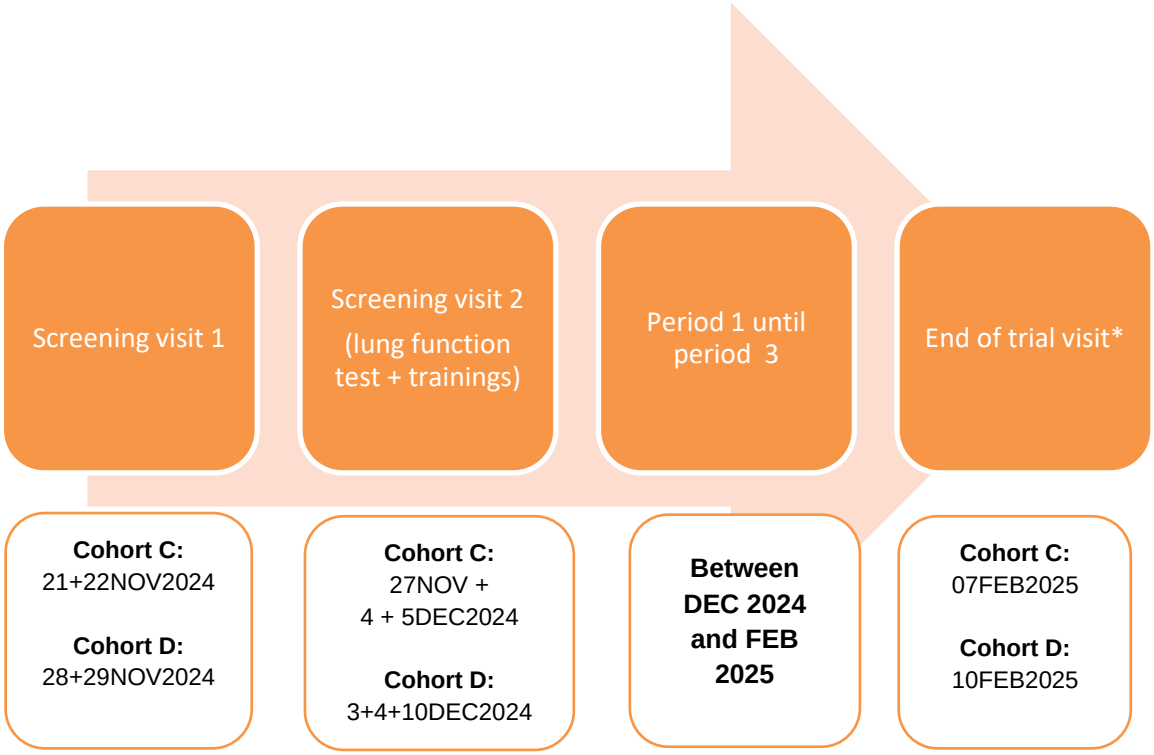
STUDY FOR THE TREATMENT OF ASTHMA

Dear pioneer,

Soon, a study to treat asthma will start at our research centre in Edegem**. In this study, medication will be administered via the lungs using an inhaler.**

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 **± 12 weeks**.



**The end of trial visit may be a telephone contact (for men) or a general examination at our centre (for women and if necessary for men).*

Study BE-80-2300237 will be conducted in maximum 5 **cohorts with approximately 16 participants per cohort.** If you are 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 (final study visit*):**
  - **Cohort C:** no later than 16NOV2024
  - **Cohort D:** no later than 18NOV2024

  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 55 years (inclusive)
- BMI: between 18.5 and 30.0 kg/m² (inclusive)
  - Weight at least 50.0 kg
- Non-smoker or stopped smoking at least 12 months prior to screening (e-cigarettes and other electronic devices should not be used for at least 6 months prior to screening)
  - You must have smoked less than 5 pack years (pack years= number of cigarette packs per day x number of years you smoked)
  - During the screening (and every period of admission), a urine test will be performed to screen for nicotine use. This means that you must stay away from smoky areas (and people who smoke) for several days beforehand.
- No medication, vitamins or homeopathic substances use until 3 weeks prior to administration of the study medication. In consultation with the physician, it may be possible to continue taking certain medications (e.g. oral contraceptives and hormone therapy during menopause) during the study.
- Contraception:
  - **Fertile women:** from screening until the end of trial visit
    - **OR with fertile male partner**: they and/or their partners must be willing to use a highly effective contraceptive method (e.g. oral contraception, shot pill, (copper) IUD…)
    - **OR with infertile male partner**: use of contraception is not required.
    - **OR** abstinence
  - **o Infertile women:**
    - **OR** postmenopausal (= no menses for at least 12 months)
    - **OR** removal of uterus
    - **OR** removal of both ovaries
    - **OR** removal of both fallopian tubes
- Be willing to perform a **lung function test** (spirometry) and training with placebo-inhaler and a specific training device during the screening visit
  - During screening visit 2, you will learn to properly use the inhaler using a placebo inhaler (a device that looks just like the device used to administer the study drug, but it does not contain the study drug) and a training device
- During the study, you will be asked to adhere to restrictions regarding physical activity, consuming grapefruit (juice), xanthine-containing (e.g. coffee, tea, chocolate, cola, etc…) and alcoholic products and poppy seeds.
- During the screening visit and on day -1 of each treatment period, an alcohol (breath test) and drug (urine) test will be taken, which must be negative.
- **Your profile is not eligible if you:**
  - Have an elevated eye pressure (narrow-angle glaucoma)
  - Have an enlarged prostate (prostatic hypertrophy)
  - Have a known urinary problem (bladder neck obstruction)
  - Have a history of respiratory problems (i.e. history of asthma, including childhood asthma)
  - Have donated or lost blood (>- 450 ml) less than 2 months prior to the screening visit or prior to administration of study medication.
  - Have unsuitable veins

COURSE OF THE STUDY

Cohort C		
Screening		
Thursday 21 November 2024 **OR** Friday 22 November 2024	Screening 1	Standard screening visit (fasted) +/-3h
Wednesday 27 November **OR** Wednesday 4 December 2024 **OR** Thursday 5 December 2024	Screening 2	Lung function test and training (+/- 1h)
Period 1		
Sunday 15 December 2024	D-1	Morning return visit and evening admission around 18h
Monday 16 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Tuesday 17 December 2024	D2	Leave the unit before noon
Wednesday 18 December 2024	D3	Return visit (+/-1h, not fasted)
Thursday 19 December 2024	D4	Return visit (+/-1h, not fasted)
Period 2		
Thursday 9 January 2025	D-1	Morning return visit and evening admission around 18h
Friday 10 January 2025	**D1**	**Stay in the unit: administration of the study medication**
Saturday 11 January 2025	D2	Leave the unit before noon
Sunday 12 January 2025	D3	Return visit (+/-1h, not fasted)
Monday 13 January 2025	D4	Return visit (+/-1h, not fasted)
Period 3		
Thursday 30 January 2025	D-1	Morning return visit and evening admission around 18h
Friday 31 January 2025	**D1**	**Stay in the unit: administration of the study medication**
Saturday 1 February 2025	D2	Leave the unit before noon
Sunday 2 February 2025	D3	Return visit (+/-1h, not fasted)
Monday 3 February 2025	D4	Return visit (+/-1h, not fasted)
End of trial visit		
Friday 7 February 2025	VD	**Women**: Standard visit (+/- 1h) **Men**: Follow-up phone call **OR** general examination* (+/- 1h)

**There will be a standard telephone contact unless the study doctor thinks it is necessary for you to come to the research center for a standard visit.*

Cohort D		
Screening		
Thursday 28 November 2024 **OR** Friday 29 November 2024	Screening 1	Standard screening visit (fasted) +/-3h
Tuesday 3 December 2024 **OR** Wednesday 4 December 2024 **OR** Tuesday 10 December 2024	Screening 2	Lung function test and training (+/- 1h)
Period 1		
Tuesday 17 December 2024	D-1	Morning return visit and evening admission around 18h
Wednesday 18 December 2024	**D1**	**Stay in the unit:** **administration of the study medication**
Thursday 19 December 2024	D2	Leave the unit before noon
Friday 20 December 2024	D3	Return visit (+/-1h, not fasted)
Saturday 21 December 2024	D4	Return visit (+/-1h, not fasted)
Period 2		
zondag 12 January 2025	D-1	Morning return visit and evening admission around 18h
maandag 13 January 2025	**D1**	**Stay in the unit:** **administration of the study medication**
Tuesday 14 January 2025	D2	Leave the unit before noon
Wednesday 15 January 2025	D3	Return visit (+/-1h, not fasted)
Thursday 16 January 2025	D4	Return visit (+/-1h, not fasted)
Period 3		
Sunday 2 February 2025	D-1	Morning return visit and evening admission around 18h
Monday 3 February 2025	**D1**	**Stay in the unit:** **administration of the study medication**
Tuesday 4 February 2025	D2	Leave the unit before noon
Wednesday 5 February 2025	D3	Return visit (+/-1h, not fasted)
Thursday 6 February 2025	D4	Return visit (+/-1h, not fasted)
End of trial visit		
Monday 10 February 2025	VD	**Women**: Standard visit (+/- 1h) **Men**: Follow-up phone call **OR** general examination* (+/- 1h)

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 2050** for completing the entire study (including screening visit and follow-up phone call)
  OR
- **€ 2100** for completing the entire study (including screening visit and end of trial 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 be done **from now** 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-80-2300237
Cohort C and/or cohort D

Last name and first name: ...
Date of birth: ...
Telephone number: ...
Start and end year of smoking + average amount of cigarettes per day: …

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 8h-12h and 13h-17h) to schedule a screening appointment, if your profile meets the inclusion criteria.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300237.

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