Revision: ***2.0 dd 19SEP2024***

STUDY NUMBER: BE-80-2400127

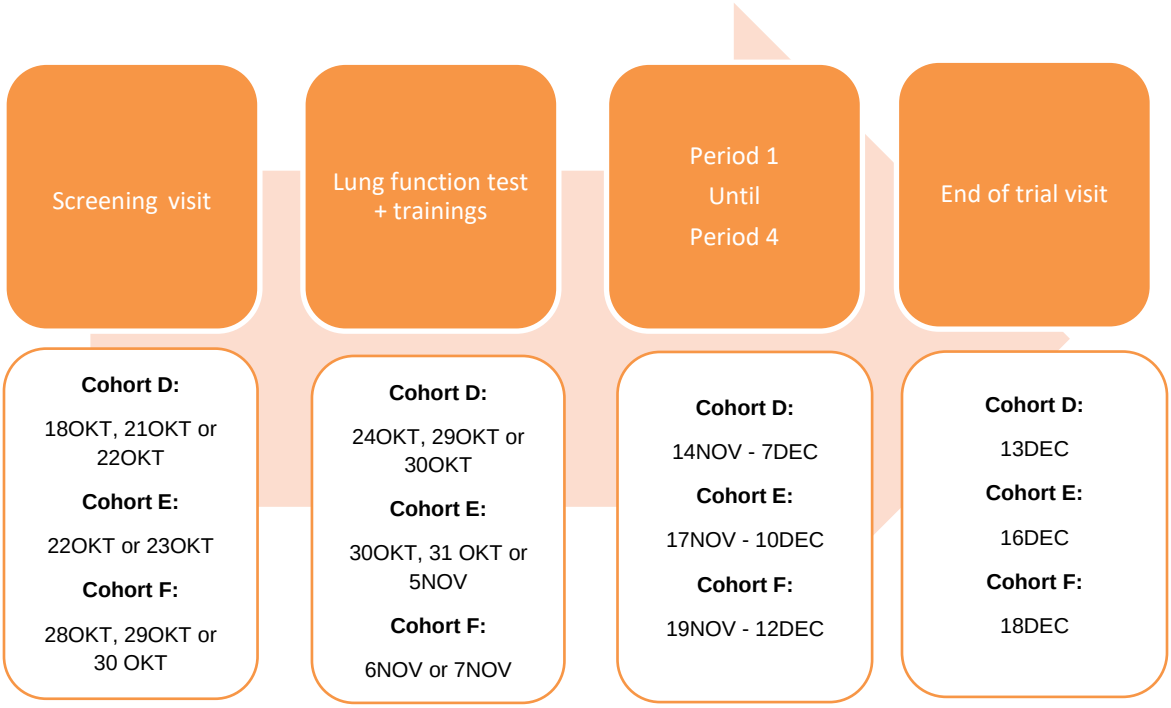
STUDY FOR THE TREATMENT OF ASTHMA

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat asthma,** the study medication will be administrated through 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 **± 10 weeks**.



Study BE-80-2400127 will be conducted in ± **6 cohorts with approximately 15 participants per cohort.** 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 (include if applicable).

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):**
  - **Cohort D no later than: 16 OKT 2024**
  - **Cohort E no later than: 19 OKT 2024**
  - **Cohort F no later than: 21 OKT2024**

  **Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men/women
- Age: between 18 and 55 years (inclusive)
- BMI: between 18,5 and 30,0 kg/m²
  - Weight of at least 50,0 kg
- Non-smokers, or ex-smokers (stopped at least 1 year before screening), (e-cigarettes and other electronic devices must be stopped at least 6 months before screening)
  - **You may not have smoked more than 5 packyears**
    (packyears = number of cigarettes per day x number of years smoked /20)
  - **During screening (and admission of each period) a cotinine test will be performed. This means that you should stay away from smoky areas (and people who smoke) for a few days beforehand.**
- 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)
  - Contraception and hormone replacement therapy (for postmenopausal women) are permitted.
- Contraception:
  - **Fertile women**: from screening until the end of trial visit
    - **OR with a 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**: contraception is not required in this case.
    - **OR** abstinence
  - **Infertile women**:
    - **OR** postmenopausal (= no menses 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)
- Be willing to perform a spirometry (**lung function test**)
- During the study, you will be asked to adhere to restrictions regarding physical activity (from 24h prior to screening), consuming grapefruit (juice) and other fruit juices, caffeinated and alcoholic products
- No participation in any of the other cohorts of this study.
- No blood donated or lost (≥ 450 ml) less than 2 months prior to the screening or prior to administration of the study medication
- **You are not eligible if you:**
  - Have a history of cardiac, hepatic, gastrointestinal, neurological, renal, hormonal, metabolic, muscular, psychiatric, or respiratory disorders (including childhood asthma, pulmonary fibrosis, bronchiectasis)
  - Have unsuitable veins for blood draw.
  - Have a history of alcohol and drug abuse within 12 months before screening.
  - Are a heavy caffeine user (with more than 5 consumptions per day) of e.g., coffee, tea, cola, …
  - Have a history of severe allergic reactions to a product (food, medicine, etc.)

COURSE OF THE STUDY

Cohort D		
Screening		
Friday 18 October, Monday 21 October of Tuesday 22 October 2024	Screening	Standard screening visit (fasted) +/-3h
Thursday 24 October, Tuesday 29 October of Thursday 31 October 2024	Screening 2	Lung function test + training (+/- 1h)
Period 1		
Thursday 14 November 2024	D-1	Admission in the afternoon
Friday 15 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Saturday 16 November 2024	D2	Go home in the morning
Period 2		
Thursday 21 November 2024	D-1	Admission in the afternoon
Friday 22 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Saturday 23 November 2024	D2	Go home in the morning
Period 3		
Thursday 28 November 2024	D-1	Admission in the afternoon
Friday 29 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Saturday 30 November 2024	D2	Go home in the morning
Period 4		
Thursday 5 December 2024	D-1	Admission in the afternoon
Friday 6 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Saturday 7 December 2024	D2	Go home in the morning
End of trial visit		
Friday 13 December 2024	VD	**Women**: Standard screening visit (+/- 1h) **Men**: Follow up phone call

Cohort E		
Screening		
Tuesday 22 of Wednesday 23 October 2024	Screening	Standard screening visit (fasted) +/-3h
Wednesday 30 October, Thursday 31 October of Tuesday 5 November 2024	Screening 2	Lung function test + training (+/- 1h)
Period 1		
Sunday 17 November 2024	D-1	Admission in the afternoon
Monday 18 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Tuesday 19 November 2024	D2	Go home in the morning
Period 2		
Sunday 24 November 2024	D-1	Admission in the afternoon
Monday 25 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Tuesday 26 November 2024	D2	Go home in the morning
Period 3		
Sunday 1 December 2024	D-1	Admission in the afternoon
Monday 2 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Tuesday 3 December 2024	D2	Go home in the morning
Period 4		
Sunday 8 December 2024	D-1	Admission in the afternoon
Monday 9 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Tuesday 10 December 2024	D2	Go home in the morning
End of trial visit		
Monday 16 December 2024	VD	**Women**: Standard screening visit (+/- 1h) **Men**: Follow up phone call

Cohort F		
Screening		
Monday 28 October, Tuesday 29 October of 30 October 2024	Screening	Standard screening visit (fasted) +/-3h
Wednesday 6 November of Thursday 7 November 2024	Screening 2	Lung function test + training (+/- 1h)
Period 1		
Tuesday 19 November 2024	D-1	Admission in the afternoon
Wednesday 20 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Thursday 21 November 2024	D2	Go home in the morning
Period 2		
Tuesday 26 November 2024	D-1	Admission in the afternoon
Wednesday 27 November 2024	**D1**	**Stay in the unit: administration of the study medication**
Thursday 28 November 2024	D2	Go home in the morning
Period 3		
Tuesday 3 December 2024	D-1	Admission in the afternoon
Wednesday 4 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Thursday 5 December 2024	D2	Go home in the morning
Period 4		
Tuesday 10 December 2024	D-1	Admission in the afternoon
Wednesday 11 December 2024	**D1**	**Stay in the unit: administration of the study medication**
Thursday 12 December 2024	D2	Go home in the morning
End of trial visit		
Wednesday 18 December 2024	VD	**Women**: Standard screening visit (+/- 1h) **Men**: Follow up phone call

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 2050** (for men) **or € 2100** (for women) 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 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-80-2400127
Cohort D, E and/or F

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.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2400127.

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