

STUDY NUMBER: BE-80-2300610

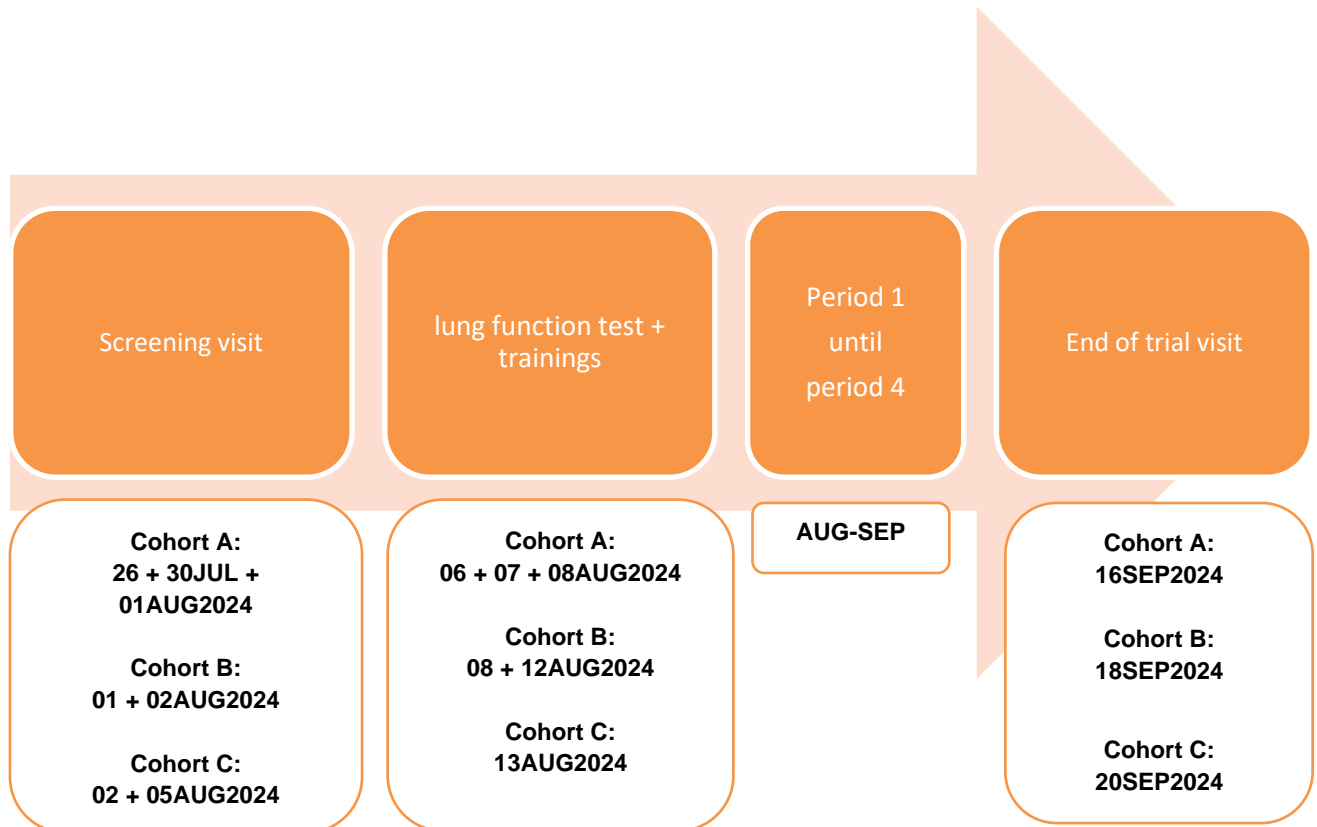
STUDY FOR THE TREATMENT OF ASTHMA AND COPD

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat asthma and COPD (chronic obstructive pulmonary disease)**, in which the study medication will be administered **via an inhaler (puffer)**.

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-80-2300610 will be conducted in **6 cohorts with 16 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.

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 A no later than: 20JUL2024**
 - **Cohort B no later than: 22JUL2024**
 - **Cohort C no later than: 24JUL2024**
- **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 (inclusive)
 - Weight of at least 50kg
- Non-smoker or stopped smoking minimum 12 months before screening (e-cigarettes and other electronic devices must be quit 6 months before screening)
 - **You must not have smoked more than 5 pack years**
(Pack years = number of cigarettes per day x number of years you smoked /20)
 - **o During the screening (and every period of admission), a cotinine test will be performed. This means that you must stay away from smoky areas (and people who smoke) for several 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:
 - **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:** contraception is not required in this case
 - **OR abstinence**
 - **o 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, consuming grapefruit (juice) and other fruit juices, caffeinated and alcoholic products
- No blood donated or lost (≥ 450 ml) less than 2 months prior to the preliminary study or prior to administration of the study medication
- **You are not eligible if you:**
 - Have a history of respiratory problems (i.e., a history of asthma, including childhood asthma)
 - **o Are a heavy caffeine user (with more than 5 consumptions per day) of e.g., coffee, tea, cola...**
 - **o Are not a good prick**
 - **o Have a history of alcohol and drug abuse within 12 months prior to screening**

COURSE OF THE STUDY

Cohort A		
Screening		
Friday 26 July 2024 OR Tuesday 30 July 2024 OR 01 August 2024	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 6 August 2024 OR Wednesday 7 August 2024 OR Thursday 8 August 2024	Screening 2	Lung function test (+/- 1h)
Period 1		
Sunday 18 August 2024	D-1	Admission in the afternoon
Monday 19 August 2024	D1	Stay in the unit: Administration of the study medication
Tuesday 20 August 2024	D2	Go home in the morning
Period 2		
Sunday 25 August 2024	D-1	Admission in the afternoon
Monday 26 August 2024	D1	Stay in the unit: Administration of the study medication
Tuesday 27 August 2024	D2	Go home in the morning
Period 3		
Sunday 1 September 2024	D-1	Admission in the afternoon
Monday 2 September 2024	D1	Stay in the unit: Administration of the study medication
Tuesday 3 September 2024	D2	Go home in the morning
Period 4		
Sunday 8 September 2024	D-1	Admission in the afternoon
Monday 9 September 2024	D1	Stay in the unit: Administration of the study medication
Tuesday 10 September 2024	D2	Go home in the morning
End of trial visit		
Monday 16 September 2024	VD	Women: Standard screening visit (+/- 1h) Men: Follow-up phone call

Cohort B		
Screening		
Thursday 1 August 2024 OR Friday 2 August 2024	Screening	Standard screening visit (fasted) +/- 3h
Thursday 8 August 2024 OR Monday 12 August 2024	Screening 2	Lung function test (+/- 1h)
Period 1		
Tuesday 20 August 2024	D-1	Admission in the afternoon
Wednesday 21 August 2024	D1	Stay in the unit: Administration of the study medication
Thursday 22 August 2024	D2	Go home in the morning
Period 2		
Tuesday 27 August 2024	D-1	Admission in the afternoon
Wednesday 28 August 2024	D1	Stay in the unit: Administration of the study medication
Thursday 29 August 2024	D2	Go home in the morning
Period 3		
Tuesday 3 September 2024	D-1	Admission in the afternoon
Wednesday 4 September 2024	D1	Stay in the unit: Administration of the study medication
Thursday 5 September 2024	D2	Go home in the morning
Period 4		
Tuesday 10 September 2024	D-1	Admission in the afternoon
Wednesday 11 September 2024	D1	Stay in the unit: Administration of the study medication
Thursday 12 September 2024	D2	Go home in the morning
End of trial visit		
Wednesday 18 September 2024	VD	Women: Standard screening visit (+/- 1h) Men: Follow-up phone call

Cohort C		
Screening		
Friday 2 August 2024 OR Monday 5 August 2024	Screening	Standard screening visit (fasted) +/- 3h
Tuesday 13 August 2024	Screening 2	Lung function test (+/- 1h)
Period 1		
Thursday 22 August 2024	D-1	Admission in the afternoon
Friday 23 August 2024	D1	Stay in the unit: Administration of the study medication
Saturday 24 August 2024	D2	Go home in the morning
Period 2		
Thursday 29 August 2024	D-1	Admission in the afternoon
Friday 30 August 2024	D1	Stay in the unit: Administration of the study medication
Saturday 31 August 2024	D2	Go home in the morning
Period 3		
Thursday 5 September 2024	D-1	Admission in the afternoon
Friday 6 September 2024	D1	Stay in the unit: Administration of the study medication
Saturday 7 September 2024	D2	Go home in the morning
Period 4		
Thursday 12 September 2024	D-1	Admission in the afternoon
Friday 13 September 2024	D1	Stay in the unit: Administration of the study medication
Saturday 14 September 2024	D2	Go home in the morning
End of trial visit		
Friday 20 September 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 (travel reimbursement excluded*)

**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 **Friday 14 June 2024 at 8h30** 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):

Studienummer: BE-80-2300610 Cohort A, Cohort B en/of Cohort C Last name and first name: ... Date of birth: ... Telephone number: ... Start and end year of smoking + average amount of cigarettes per day: ...
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Please note that registrations before 8h30 will not be registered. In addition, you can only register for 1 person at the same time.

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

From Wednesday 19 June 2024 we will call the **99 first registrations** between 8h and 17h.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300610.

SGS CPU

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