Revision: ***2.0 08AUG2024***

STUDY NUMBER: BE-80-2300670

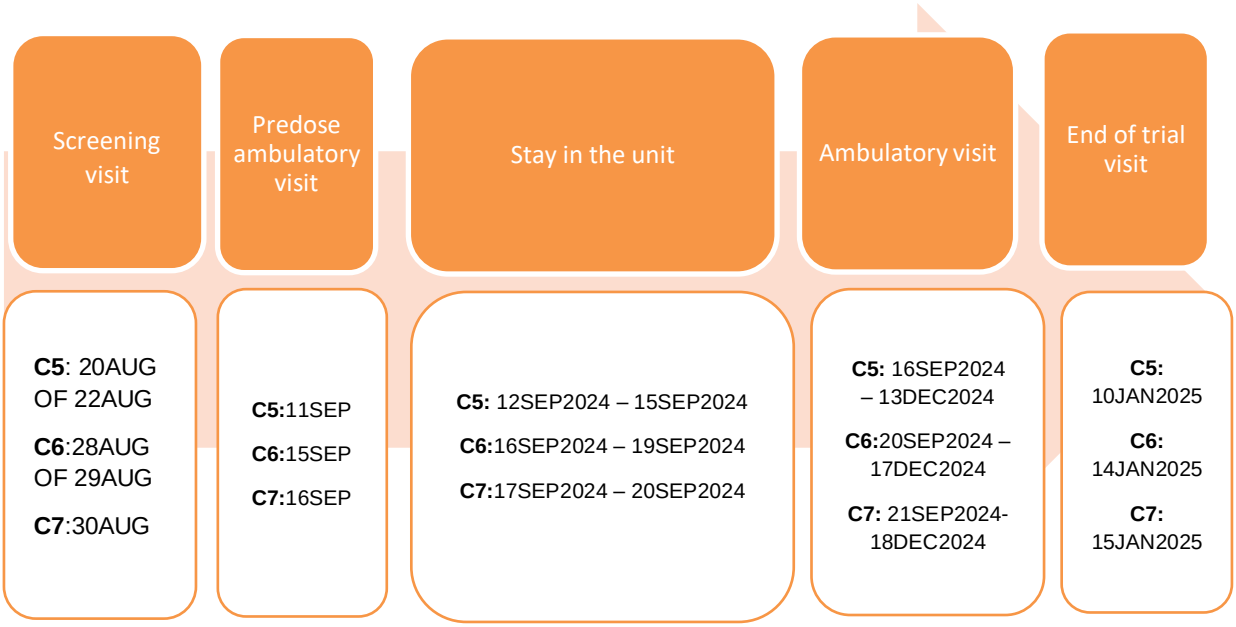
STUDY FOR THE TREATMENT OF CHRONIC INFLAMMATION OF THE SKIN

Dear pioneer,

Soon, a study will start at our research centre in Edegem **to treat chronic inflammation of the skin.**

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 **± 21 weeks**.



Study BE-80-2300670 will be conducted in **8 cohorts.** This letter contains information about **cohort 5, 6 and 7.** You can find the details further in this recruitment letter. If interested, you can let us know your preferred cohort and ultimately you can only participate in one cohort.

Selected as a reserve? Then you will enter the unit and you may go home when everyone is dosed. If someone drops out, you are able to participate in the full study and take that person's place. During the period, you adhere to the study requirements.

INCLUSION CRITERIA

- **Last participation in other clinical trial (Last study medication*):**
  - **Cohort 5** not later than**: 21JUN2024**
  - **Cohort 6** not later than: **29JUN2024**
  - **Cohort 7** not later than: **01JUL2024**

  **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 50 years old (**inclusive**)
- BMI: between 18.5 and 30.0 kg/m² (**inclusive**)
  - minimum weight of 40kg
- Non-smoker, ex-smoker or smoking maximum 10 cigarettes (including electronic cigarettes), 3 cigars or 3 pipes per day
- Not using any medication, vitamins, or homeopathic substances (the use of specific medication could be allowed during the study, but this must be first discussed with the investigator)
- Contraception: should be used from 30 days before and up to 16 weeks after dosing
  - **Fertile women:**
    - Use combined hormonal contraception (e.g.: pill, vaginal ring, hormone patch, etc.)
    - **OR** contraception with only progestogen (e.g.: minipill, injection, hormone rod...)
    - **OR** IUD (hormonal or copper)
    - **OR** your male partner has had a vasectomy
    - **OR** abstinence
  - **Infertile women:**
    - Postmenopausal (without menstruation for at least 12 months)
    - **OR** sterilized
    - **OR** bilateral tubal occlusion/ligation
    - **OR** bilateral ovariectomy (removal of both ovaries)
- **Be willing to:**
  - Not to smoke during your stay in the unit and a maximum of 10 cigarettes per day during the rest of the trial
  - Not to donate blood of more than 100 ml within 30 days before administration of the study medication or donating blood during the study
  - Do not use products containing **poppy seeds** from 2 days before screening and from 2 days before admission
  - Do not drink alcohol from 3 days before admission
  - No physical exercises from 7 days before administration of study medication until a maximum of 4 weeks after administration
- **No prior participation in one of the previous cohorts of this study**
- **Your profile is not eligible if you:**
  - Have gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunological, or hormonal disorders
  - Have diseases of the central nervous system (including but not limited to any form of seizure or stroke) or other relevant neurological or psychiatric disorders
  - Have a history of orthostatic, hypotension, fainting or blackouts
  - Have a history of allergy or hypersensitivity
  - Have a history of additional risk factors for a cardiac arrhythmia (such as heart failure, or family history of long QT syndrome)
  - Have ever had a severe allergic reaction
  - Have a history of tuberculosis or have ever tested positive for tuberculosis test (QuantiFERON test)

COURSE OF THE STUDY

Cohort 5		
Screening		
Tuesday 20 August 2024 OR Thursday 22 August 2024	Screening	Standard screening visit (fasted +/-3u)
Treatment period 1		
Wednesday 11 September 2024	D-2	Morning visit (fasted)
Thursday 12 September 2024	D-1	Evening admission around 18h
Friday 13 September 2024	**D1**	**Stay in the unit: administration of the study medication**
Saturday 14 September 2024	D2	Stay in the unit
Sunday 15 September 2024	D3	Going home
Monday 16 September 2024	D4	Return visit
Friday 20 September 2024	D8	Return visit (fasted)
Monday 23 September 2024	D11	Return visit
Friday 27 September 2024	D15	Return visit
Friday 4 October 2024	D22	Return visit (fasted)
Friday 11 oktober 2024	D29	Return visit
Friday 25 October 2024	D43	Return visit
Friday 8 November 2024	D57	Return visit
Friday 22 November 2024	D71	Return visit
Friday 13 December 2024	D92	Return visit
End of trial visit		
Friday 10 January 2025	VD	Standard examination (fasted +/- 3h)

Cohort 6		
Screening		
Wednesday 28 August 2024 OR Thursday 29 August 2024	Screening	Standard screening visit (fasted +/-3u)
Treatment periode 1		
Sunday 15 September 2024	D-2	Morning visit (fasted)
Monday 16 September 2024	D-1	Evening admission around 18h
Tuesday 17 September 2024	**D1**	**Stay in the unit: administration of the study medication**
Wednesday 18 September 2024	D2	Stay in the unit
Thursday 19 September 2024	D3	Going home
Friday 20 September 2024	D4	Return visit
Tuesday 24 September 2024	D8	Return visit (fasted)
Thursday 26 September 2024	D10	Return visit
Tuesday 1 October 2024	D15	Return visit
Tuesday 8 October 2024	D22	Return visit (fasted)
Tuesday 15 October 2024	D29	Return visit
Tuesday 29 October 2024	D43	Return visit
Tuesday 12 November 2024	D57	Return visit
Tuesday 26 November 2024	D71	Return visit
Tuesday 17 December 2024	D92	Return visit
End of trial visit		
Tuesday 14 January 2025	VD	Standard examination (fasted +/- 3h)

Cohort 7		
Screening		
Friday 30 August 2024	Screening	Standard screening visit (fasted +/-3u)
Treatment period 1		
Monday 16 September 2024	D-2	Morning return (fasted)
Tuesday 17 September 2024	D-1	Evening admission around 18h
Wednesday 18 September 2024	**D1**	**Stay in the unit: administration of the study medication**
Thursday 19 September 2024	D2	Stay in the unit
Friday 20 September 2024	D3	Going home
Saturday 21 September 2024	D4	Return visit
Wednesday 25 September 2024	D8	Return visit (fasted)
Saturday 28 September 2024	D11	Return visit
Wednesday 2 October 2024	D15	Return visit
Wednesday 9 October 2024	D22	Return visit (fasted)
Wednesday 16 October 2024	D29	Return visit
Wednesday 30 October 2024	D43	Return visit
Wednesday 13 November 2024	D57	Return visit
Wednesday 27 November 2024	D71	Return visit
Wednesday 18 December 2024	D92	Return visit
End of trial visit		
Wednesday 15 january 2025	VD	Standard examination (fasted +/- 3h)

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 2600** for completing the entire study (including selection visit)
- **€ 400** for reserve volunteers (including selection visit)
- **€ 50** for the selection 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 day 1. 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-80-2300670**
Cohort 5,6 or 7

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-80-2300670.

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