

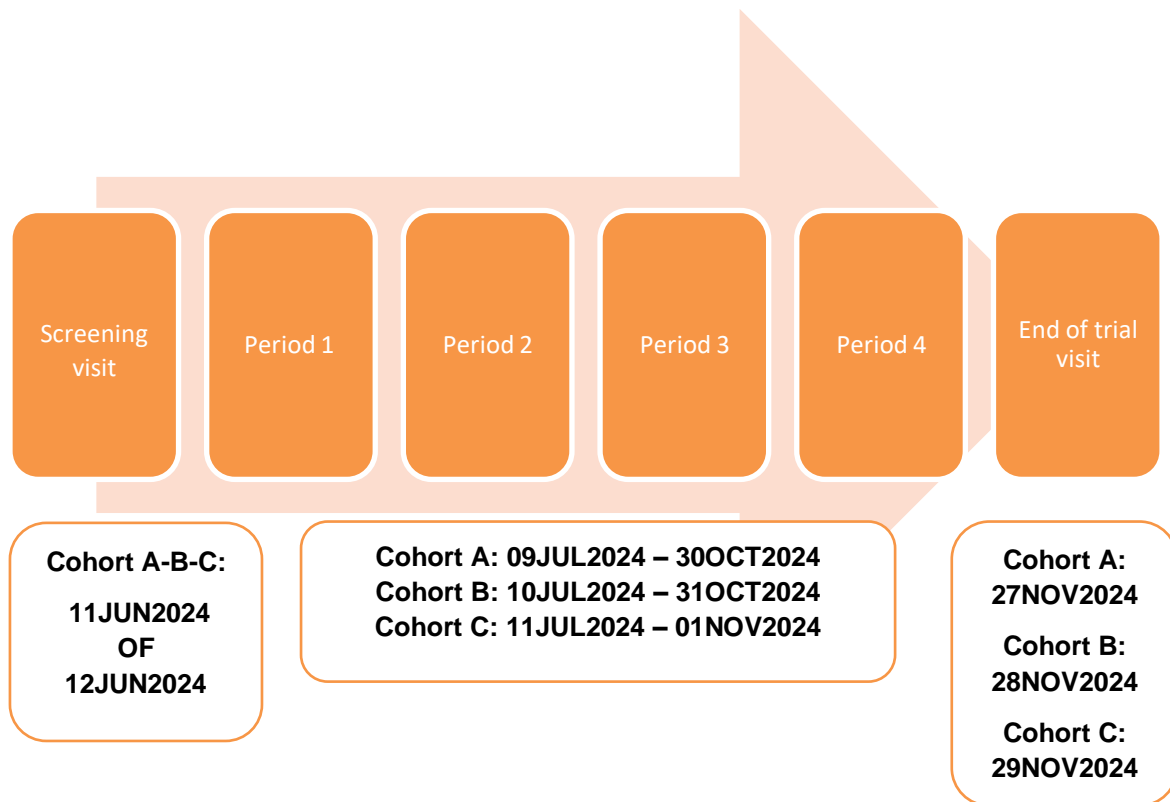
STUDY NUMBER: BE-80-2300065**STUDY FOR THE TREATMENT OF PROGRESSIVE PULMONARY FIBROSIS**

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat progressive pulmonary fibrosis. Pulmonary fibrosis is a lung disease where normal lung tissue is progressively replaced by scar tissue.**

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 **± 6months**.



* Fixed fee. In addition, you will receive reimbursement for your travel expenses, which is set at € 0,3542 per km, with a maximum of 120 km (one way).

Study BE-80-2300065 will be conducted in **4 dose groups with 10 subjects each. Each dose group is divided into 3 cohorts of 2, 2 and 6 subjects.** You can find the details further in this recruitment letter. If interested, you can let us know your preferred group/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*):**
 - **Dose group 2 cohort A: not later than 11MAY2024**
 - **Dose group 2 cohort B: not later than 12MAY2024**
 - **Dose group 2 cohort C: not later than 13MAY2024**

**Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- **Healthy man**
- Age: between 18 and 55 years (inclusive)
- BMI: between 18.5 and 29.9 kg/m² (inclusive)
- Non-smoker, ex-smoker or smoke a maximum of 5 cigarettes, 1 cigar or 1 pipe per day
 - Smoking is not allowed during your overnight stay at SGS
- 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:
 - Men: (from screening until the end of trial visit)
 - Use of a condom in combination with an effective contraception method (if your female partner is fertile)
 - **OR** abstinence
 - **OR** vasectomy combined with the use of a condom (if your female partner is fertile)
- **You are willing to:**
 - not donate sperm from screening until completion of the end of trial visit.
 - not consume caffeinated and xanthine-containing beverages (e.g. energy drinks, coffee, cola, tea) from 4h before admission and on all in-house days.
 - not consume alcoholic beverages, dietary supplements and products containing St. John's Wort from 4 days before the first administration of the study medication until discharge on Day 31
 - Alcohol intake during ambulatory part of the trial should not exceed 3 units/day.
 - avoid excessive physical activities from 7 days before the first administration of the study medication until the end of trial visit
- **Your profile is not eligible if you:**
 - have donated or lost blood (due to an operation, accident, ...) in the 30 days before the first administration of the study medication or if you intend to donate blood during the study
 - have gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunological, psychiatric, neurological or hormonal disorders
 - have been in contact with Tuberculosis
 - **were dosed in study BE-80-2100805**

REMUNERATION * FOR YOUR ENGAGEMENT

- **€ 5000** 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*

Payment of those who are screen failures & reserves will be started after dosing. When you are effectively a study participant, payment will start after your final study. 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 on the reason for early termination. This decision will be made jointly by the SGS study team.

COURSE OF THE STUDY

Dose group 2 cohort A		
Screening		
Tuesday 11 June 2024 OR Wednesday 12 June 2024	Screening	Standard screening visit (fasted ; +/- 3h)
Studie		
Tuesday 9 July 2024	D-1	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Wednesday 10 July 2024	D1	Stay in the unit: administration of the study medication
Thursday 11 July 2024	D2	Stay in the unit
Friday 12 July 2024	D3	Go home in the morning
Sunday 14 July 2024	D5	Morning return (not fasted, +/- 1h)
Tuesday 16 July 2024	D7	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Wednesday 17 July 2024	D8	Stay in the unit: administration of the study medication
Thursday 18 July 2024	D9	Stay in the unit
Friday 19 July 2024	D10	Go home in the morning
Sunday 21 July 2024	D12	Morning return (not fasted, +/- 1h)
Tuesday 23 July 2024	D14	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Wednesday 24 July 2024	D15	Stay in the unit: administration of the study medication
Thursday 25 July 2024	D16	Stay in the unit
Friday 26 July 2024	D17	Go home in the morning
Saturday 28 July 2024	D19	Morning return (not fasted, +/- 1h)
Tuesday 30 July 2024	D21	Morning return (not fasted, +/- 1h)
Thursday 2 August 2024	D24	Morning return (not fasted, +/- 1h)
Tuesday 6 August 2024	D28	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Wednesday 7 August 2024	D29	Stay in the unit: administration of the study medication
Thursday 8 August 2024	D30	Stay in the unit
Friday 9 August 2024	D31	Go home in the morning
Sunday 11 August 2024	D33	Morning return (not fasted, +/- 1h)
Wednesday 14 August 2024	D36	Morning return (not fasted, +/- 1h)
Wednesday 21 August 2024	D43	Morning return (not fasted, +/- 1h)
Wednesday 28 August 2024	D50	Morning return (not fasted, +/- 1h)
Wednesday 4 September 2024	D57	Morning return (fasted , +/- 1h)
Wednesday 2 October 2024	D85	Morning return (fasted , +/- 1h)
Wednesday 30 October 2024	D113	Morning return (fasted , +/- 1h)
End of trial		
Wednesday 27 November 2024	VD	Standard examination (fasted ; +/- 3h)

Dose group 2 cohort B		
Screening		
Tuesday 11 June 2024 OR Wednesday 12 June 2024	Screening	Standard screening visit (fasted ; +/- 3h)
Studie		
Wednesday 10 July 2024	D-1	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Thursday 11 July 2024	D1	Stay in the unit: administration of the study medication
Friday 12 July 2024	D2	Stay in the unit
Saturday 13 July 2024	D3	Go home in the morning
Monday 15 July 2024	D5	Morning return (not fasted, +/- 1h)
Wednesday 17 July 2024	D7	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Thursday 18 July 2024	D8	Stay in the unit: administration of the study medication
Friday 19 July 2024	D9	Stay in the unit
Saturday 20 July 2024	D10	Go home in the morning
Monday 22 July 2024	D12	Morning return (not fasted, +/- 1h)
Wednesday 24 July 2024	D14	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Thursday 25 July 2024	D15	Stay in the unit: administration of the study medication
Friday 26 July 2024	D16	Stay in the unit
Saturday 27 July 2024	D17	Go home in the morning
Monday 29 July 2024	D19	Morning return (not fasted, +/- 1h)
Wednesday 31 July 2024	D21	Morning return (not fasted, +/- 1h)
Saturday 3 August 2024	D24	Morning return (not fasted, +/- 1h)
Wednesday 7 August 2024	D28	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Thursday 8 August 2024	D29	Stay in the unit: administration of the study medication
Friday 9 August 2024	D30	Stay in the unit
Saturday 10 August 2024	D31	Go home in the morning
Monday 12 August 2024	D33	Morning return (not fasted, +/- 1h)
Thursday 15 August 2024	D36	Morning return (not fasted, +/- 1h)
Thursday 22 August 2024	D43	Morning return (not fasted, +/- 1h)
Thursday 29 August 2024	D50	Morning return (not fasted, +/- 1h)
Thursday 5 September 2024	D57	Morning return (fasted , +/- 1h)
Thursday 3 October 2024	D85	Morning return (fasted , +/- 1h)
Thursday 31 October 2024	D113	Morning return (fasted , +/- 1h)
End of trial		
Thursday 28 November 2024	VD	Standard examination (fasted ; +/- 3h)

Dose group 2 cohort C		
Screening		
Tuesday 11 June 2024 OR Wednesday 12 June 2024	Screening	Standard screening visit (fasted ; +/- 3h)
Studie		
Thursday 11 July 2024	D-1	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Friday 12 July 2024	D1	Stay in the unit: administration of the study medication
Saturday 13 July 2024	D2	Stay in the unit
Sunday 14 July 2024	D3	Go home in the morning
Tuesday 16 July 2024	D5	Morning return (not fasted, +/- 1h)
Thursday 18 July 2024	D7	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Friday 19 July 2024	D8	Stay in the unit: administration of the study medication
Saturday 20 July 2024	D9	Stay in the unit
Sunday 21 July 2024	D10	Go home in the morning
Tuesday 23 July 2024	D12	Morning return (not fasted, +/- 1h)
Thursday 25 July 2024	D14	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Friday 26 July 2024	D15	Stay in the unit: administration of the study medication
Saturday 27 July 2024	D16	Stay in the unit
Sunday 28 July 2024	D17	Go home in the morning
Tuesday 30 July 2024	D19	Morning return (not fasted, +/- 1h)
Thursday 1 August 2024	D21	Morning return (not fasted, +/- 1h)
Sunday 4 August 2024	D24	Morning return (not fasted, +/- 1h)
Thursday 8 August 2024	D28	Morning return (fasted ; +/- 1h) and admission to the unit in the afternoon (18h)
Friday 9 August 2024	D29	Stay in the unit: administration of the study medication
Saturday 10 August 2024	D30	Stay in the unit
Sunday 11 August 2024	D31	Go home in the morning
Tuesday 13 August 2024	D33	Morning return (not fasted, +/- 1h)
Friday 16 August 2024	D36	Morning return (not fasted, +/- 1h)
Friday 23 August 2024	D43	Morning return (not fasted, +/- 1h)
Friday 30 August 2024	D50	Morning return (not fasted, +/- 1h)
Friday 6 September 2024	D57	Morning return (fasted , +/- 1h)
Friday 4 October 2024	D85	Morning return (fasted , +/- 1h)
Friday 1 November 2024	D113	Morning return (fasted , +/- 1h)
End of trial		
Friday 29 November 2024	VD	Standard examination (fasted ; +/- 3h)

INTEREST IN PARTICIPATING

Registration for this study only indicates your interest and does not obligate you or us to participate.

Registration can be done from **Friday 3 May 2024 at 8h30** by emailing the information below to pionier@sgs.com or calling number **+32 (0)3 217 21 72** (between 8h30-12h and 13h-17h):

Study number: BE-80-2300065
Dose group 2 cohort A, B or C

Last name and first name: ...
Date of birth: ...
Telephone number: ...

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 further processing of your profile for this

From **Monday 6 May 2024** we will call the first **28** registrations between **8h30 and 17h**.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300065.

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