

**STUDY NUMBER: BE-80-2300065**

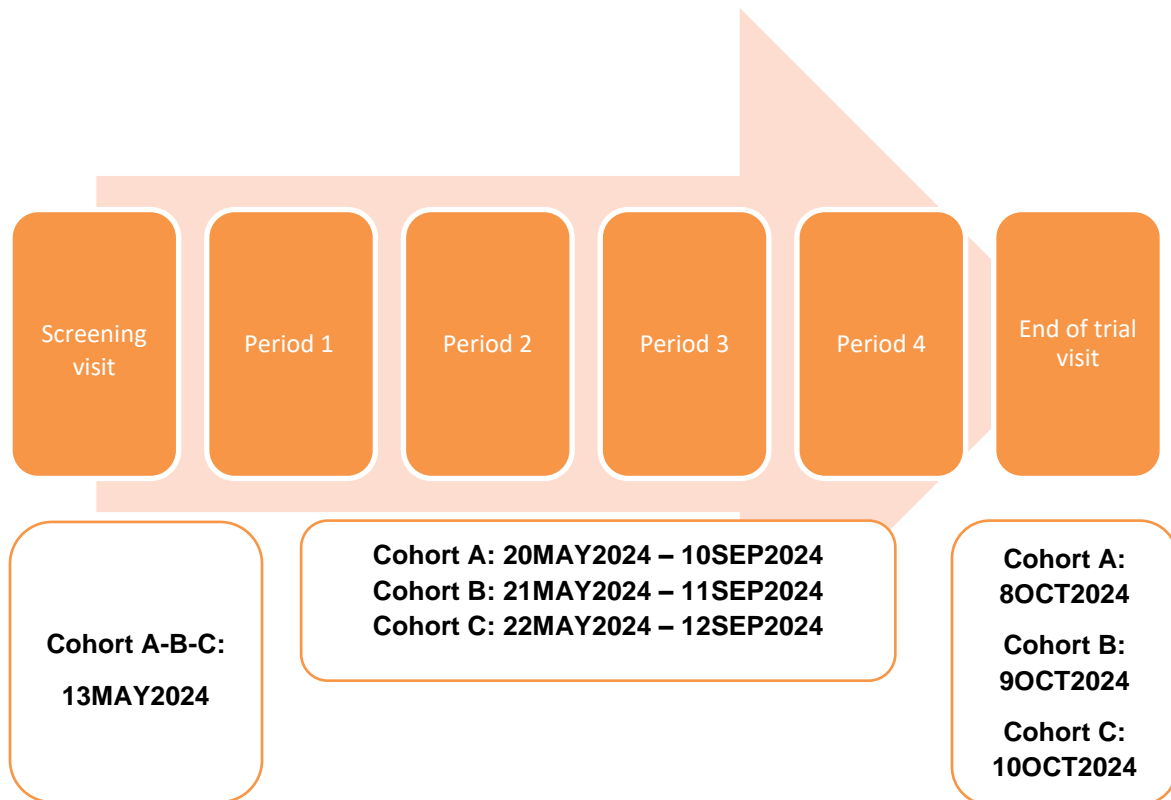
**STUDY FOR THE TREATMENT OF PROGRESSIVE PULMONARY FIBROSIS**

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**.



**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 1 cohort A: not later than 22MAR2024**
  - **Dose group 1 cohort B: not later than 23MAR2024**
  - **Dose group 1 cohort C: not later than 24MAR2024**
- *\*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/m<sup>2</sup> (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**

<b>Dose group 1 cohort A</b>		
<b>Screening</b>		
<b>Monday 13 May 2024</b>	Screening	Standard screening visit ( <b>fasted</b> ) +/- 3h
<b>Study</b>		
Monday 20 May 2024	D-1	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Tuesday 21 May 2024</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication Period 1</b>
Wednesday 22 May 2024	D2	Stay in the unit
Thursday 23 May 2024	D3	Go home around 11h
Saturday 25 May 2024	D5	Morning return (not fasted) +/- 1h
Monday 27 May 2024	D7	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Tuesday 28 May 2024</b>	<b>D8</b>	<b>Stay in the unit: administration of the study medication Period 2</b>
Wednesday 29 May 2024	D9	Stay in the unit
Thursday 30 May 2024	D10	Go home around 11h
Saturday 1 June 2024	D12	Morning return (not fasted) +/- 1h
Monday 3 June 2024	D14	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Tuesday 4 June 2024</b>	<b>D15</b>	<b>Stay in the unit: administration of the study medication Period 3</b>
Wednesday 5 June 2024	D16	Stay in the unit
Thursday 6 June 2024	D17	Go home around 11h
Saturday 8 June 2024	D19	Morning return (not fasted) +/- 1h
Monday 10 June 2024	D21	Morning return (not fasted) +/- 1h
Thursday 13 June 2024	D24	Morning return (not fasted) +/- 1h
Monday 17 June 2024	D28	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Tuesday 18 June 2024</b>	<b>D29</b>	<b>Stay in the unit: administration of the study medication Period 4</b>
Wednesday 19 June 2024	D30	Stay in the unit
Thursday 20 June 2024	D31	Go home around 11h
Saturday 22 June 2024	D33	Morning return (not fasted) +/- 1h
Tuesday 25 June 2024	D36	Morning return (not fasted) +/- 1h
Tuesday 2 July 2024	D43	Morning return (not fasted) +/- 1h
Tuesday 9 July 2024	D50	Morning return (not fasted) +/- 1h
Tuesday 16 July 2024	D57	Morning return ( <b>fasted</b> ) +/- 1h
Tuesday 13 August 2024	D85	Morning return ( <b>fasted</b> ) +/- 1h
Tuesday 10 September 2024	D113	Morning return ( <b>fasted</b> ) +/- 1h
<b>End of trial visit</b>		
Tuesday 8 October 2024	VD	Standard examination ( <b>fasted</b> ) +/- 3h

<b>Dose group 1 cohort B</b>		
<b>Screening</b>		
<b>Monday 13 May 2024</b>	Screening	Standard screening visit ( <b>fasted</b> ) +/- 3h
<b>Study</b>		
Tuesday 21 May 2024	D-1	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Wednesday 22 May 2024</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication Period 1</b>
Thursday 23 May 2024	D2	Stay in the unit
Friday 24 May 2024	D3	Go home around 11h
Sunday 26 May 2024	D5	Morning return (not fasted) +/- 1h
Tuesday 28 May 2024	D7	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Wednesday 29 May 2024</b>	<b>D8</b>	<b>Stay in the unit: administration of the study medication Period 2</b>
Thursday 30 May 2024	D9	Stay in the unit
Friday 31 May 2024	D10	Go home around 11h
Sunday 2 June 2024	D12	Morning return (not fasted) +/- 1h
Tuesday 4 June 2024	D14	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Wednesday 5 June 2024</b>	<b>D15</b>	<b>Stay in the unit: administration of the study medication Period 3</b>
Thursday 6 June 2024	D16	Stay in the unit
Friday 7 June 2024	D17	Go home around 11h
Sunday 9 June 2024	D19	Morning return (not fasted) +/- 1h
Tuesday 11 June 2024	D21	Morning return (not fasted) +/- 1h
Friday 14 June 2024	D24	Morning return (not fasted) +/- 1h
Tuesday 18 June 2024	D28	Morning return ( <b>fasted</b> ) +/- 1h Admission to the unit around 18h
<b>Wednesday 19 June 2024</b>	<b>D29</b>	<b>Stay in the unit: administration of the study medication Period 4</b>
Thursday 20 June 2024	D30	Stay in the unit
Friday 21 June 2024	D31	Go home around 11h
Sunday 23 June 2024	D33	Morning return (not fasted) +/- 1h
Wednesday 26 June 2024	D36	Morning return (not fasted) +/- 1h
Wednesday 3 July 2024	D43	Morning return (not fasted) +/- 1h
Wednesday 10 July 2024	D50	Morning return (not fasted) +/- 1h
Wednesday 17 July 2024	D57	Morning return ( <b>fasted</b> ) +/- 1h
Wednesday 14 August 2024	D85	Morning return ( <b>fasted</b> ) +/- 1h
Wednesday 11 September 2024	D113	Morning return ( <b>fasted</b> ) +/- 1h
<b>End of trial visit</b>		
Wednesday 9 October 2024	VD	Standard screening visit ( <b>fasted</b> ) +/- 3h

<b>Dose group 1 cohort C</b>		
<b>Screening</b>		
<b>Monday 13 May 2024</b>	Screening	Standard screening visit <b>(fasted)</b> +/- 3h
<b>Study</b>		
Wednesday 22 May 2024	D-1	Morning return <b>(fasted)</b> +/- 1h Admission to the unit around 18h
<b>Thursday 23 May 2024</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication Period 1</b>
Friday 24 May 2024	D2	Stay in the unit
Saturday 25 May 2024	D3	Go home around 11h
Monday 27 May 2024	D5	Morning return (not fasted) +/- 1h
Wednesday 29 May 2024	D7	Morning return <b>(fasted)</b> +/- 1h Admission to the unit around 18h
<b>Thursday 30 May 2024</b>	<b>D8</b>	<b>Stay in the unit: administration of the study medication Period 2</b>
Friday 31 May 2024	D9	Stay in the unit
Saturday 1 June 2024	D10	Go home around 11h
Monday 3 June 2024	D12	Morning return (not fasted) +/- 1h
Wednesday 5 June 2024	D14	Morning return <b>(fasted)</b> +/- 1h Admission to the unit around 18h
<b>Thursday 6 June 2024</b>	<b>D15</b>	<b>Stay in the unit: administration of the study medication Period 3</b>
Friday 7 June 2024	D16	Stay in the unit
Saturday 8 June 2024	D17	Go home around 11h
Monday 10 June 2024	D19	Morning return (not fasted) +/- 1h
Wednesday 12 June 2024	D21	Morning return (not fasted) +/- 1h
Saturday 15 June 2024	D24	Morning return (not fasted) +/- 1h
Wednesday 19 June 2024	D28	Morning return <b>(fasted)</b> +/- 1h Admission to the unit around 18h
<b>Thursday 20 June 2024</b>	<b>D29</b>	<b>Stay in the unit: administration of the study medication Period 4</b>
Friday 21 June 2024	D30	Stay in the unit
Saturday 22 June 2024	D31	Go home around 11h
Monday 24 June 2024	D33	Morning return (not fasted) +/- 1h
Thursday 27 June 2024	D36	Morning return (not fasted) +/- 1h
Thursday 4 July 2024	D43	Morning return (not fasted) +/- 1h
Thursday 11 July 2024	D50	Morning return (not fasted) +/- 1h
Thursday 18 July 2024	D57	Morning return <b>(fasted)</b> +/- 1h
Thursday 15 August 2024	D85	Morning return <b>(fasted)</b> +/- 1h
Thursday 12 September 2024	D113	Morning return <b>(fasted)</b> +/- 1h
<b>End of trial visit</b>		
Thursday 10 October 2024	VD	Standard screening visit <b>(fasted)</b> +/- 3h

### **INTEREST IN PARTICIPATING**

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

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

Study number: BE-80-2300065  
**Dose group 1 cohort A, B, or C**

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

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

We will call you as soon as possible to schedule an appointment for the screening visit, provided you are eligible for the study.

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

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