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STUDY MEDICATION IN DEVELOPMENT FOR A LIVER DISEASE

SGS – Clinical Research
Clinical Pharmacology Unit
UZA – SGS - Gebouw J
Drie Eikenstraat 655
B-2650 Edegem
03 217 21 72
be.pionier@sgs.com

Study number: BE-80-2300103 Part B

Dear pioneer,

We are looking for volunteers for a study with study medication in development for a **liver disease**.

The study consists of part A and part B. **Part A** consists of 6 groups and **part B** consists of 1 group. The groups for part A consist of 8 persons and is divided into 3 sub cohorts with 2-2-4 persons. Part B consists of 1 group of 15 people and is divided into 3 sub cohorts with 3-3-9 people. You can register for multiple groups but only participate in 1 group.

This letter contains information only about part B **dose group 7 cohort 2 NEW**. **Part B** runs over a period of \pm 20 weeks.

The study medication will be **administered intravenously (directly into a vein in your arm)**.

The trial contains:

- A screening visit + holter visit
 - A holter is a small device attached to your body for 24h to monitor heart function.
 - This device will be hooked up at the unit and after 24 hours you will need to return to the unit to disconnect the device. While wearing the device, you are asked to avoid physical exertion. In addition, you cannot swim, shower or bathe while wearing the holter.
- 3 periods of which:
 - Period 1 consists of a stay of 6 days and 5 nights
 - Period 2 and 3 consist of a stay of 5 days and 4 nights
- 13 morning return visits (short visit to our unit)
- An end of trial visit

If you refer a family member or friend who is not yet part of our database and has participated in a screening visit, SGS will offer you a voucher worth of **€ 50**. Please follow up yourself if you have a right to this voucher. This voucher can only be picked up at the recruitment team.

With kind regards,
The SGS recruitment team

ADMISSION REQUIREMENTS

- Healthy men
- Age between 18 and 55 years (inclusive)
- BMI between 19.0 and 28.0 kg/m² (inclusive)
 - Minimum weight: 65 kg on the day of screening
- Non-smoker or ex-smoker in the last 10 years or you may not have smoked for more than 10 pack years (pack years = number of cigarettes per day x number of years you have smoked divided by 20)
- No use of medication, vitamins, or homeopathic products (in consultation with the physician it could be possible that the use of specific medication is allowed during the trial)
- **Last participation in another clinical trial (last study drug intake):**
 - **Dose group 7 Cohort 2 NEW: 23OCT2024**
- **Contraception:** from administration of the study medication until 60 days after the last administration:
 - **OR** abstinence
 - **OR** use of a condom (if partner is fertile)
- **Be willing to:**
 - Wear a holter several times for 24 hours (a small device attached to your body for 24h to monitor heart function).
This device is connected in the unit and after 24 hours you must come back to disconnect the device. While wearing the device, you are asked to avoid physical exertion. In addition, you cannot swim, shower or bathe while wearing the holter.
 - It is not permitted to donate more than 100 ml of blood within 30 days prior to the scheduled administration of the study medication or an intended blood draw during the study
 - Not donate sperm 'from administration of study medication until 60 days after the last administration of the study medication
 - Not do strenuous exercise from 5 days before each administration of the study medication until end of trial visit
 - Not consume products containing methylxanthine (such as tea, coffee, cola, energy drinks or chocolate) from 12 hours before each administration of the study medication until you are discharged from the clinical center.
 - Not consume alcohol from signing the informed consent form until the end of trial visit
 - Not consume the following products from 5 days before each administration of the study medication until the visit at the end of the study: grapefruit, grapefruit juice, Seville oranges (sour or bitter oranges) and their juice, dietary supplements and products containing St. John's wort (*Hypericum perforatum*).
 - Not get exposed to the sun or solarium radiation from the administration of the study medication up to and including the end of trial visit

- **You are not eligible if you:**
 - Have a history of hypotension, fainting or blackouts
 - Have a history of neurological or psychiatric disorders (e.g., depression, CVA)
 - Have a history of cancer (less than 5 years ago)
 - Have a history of diabetes or cardiovascular disease (e.g. stroke, heart attack etc.)
 - Have an open (abrasive) wound
 - Has had minor procedures such as removal of moles or dental procedures in the last 3 months and has procedures planned in the period of the study
 - Had major surgeries in the last 6 months and had procedures planned in the period of the study

TAX FREE COMPENSATION

- **€ 5300** for the entire trial (including screening visit)
- **€ 550** for reserve participants who are admitted to the unit for an in house stay (including screening visit)
- **€ 50** for the screening visit
- **€ 125** for the screening + holter visit
- **€ 75** recheck holter

You will receive a travel compensation of € 0.3542 per km, with a max. of 120 km (one way)

The payment of a reserve compensation and/or screening compensation will be initiated after the start of the group/cohort. If you are an effective participant, the payment will be initiated after your last study visit. The standard payment term takes +/- 4 to 6 weeks.

ATTENTION:

- In case of an early termination of the trial this compensation can be adapted based on the actual duration of participation.

REGISTRATION

Would you like to register?

➤ **STEP 1**

Send an e-mail **NOW** to:

pionier@sgs.com

OR

Call **NOW**:

+32 (0)3 217 21 72

(Calling is only possible between 08:30h and 17:00h)

You can only register 1 person per e-mail.

The timing of your registration determines the final order in the trial.

➤ **STEP 2**

Please mention the following information:

- **BE-80-2300103 Dose group 7 – cohort 2 NEW**
- First and last name
- Birth date
- Telephone number

➤ **STEP 3**

We call the first **18 registrations** as soon as possible to schedule a screening appointment.

Your reaction to this letter merely indicates your interest and does not obligate you nor us to registration or (acceptance of your request to) participation.

STUDY COURSE

Dose group 7 Cohort 2 NEW		
Screening		
Monday 28 October 2024 OR Tuesday 29 October 2024 OR Wednesday 30 October 2024 OR Monday 4 November 2024	Screening	Standard screening visit (fasted) +/- 3h + connection of the holter device
Tuesday 29 October 2024 OR Wednesday 30 October 2024 OR Thursday 31 October 2024 OR Tuesday 5 November 2024	Holter	Short visit to return the holter
Period 1		
Wednesday 20 November 2024	D-2	Admission to the unit in the afternoon
Thursday 21 November 2024	D-1	Stay in the unit
Friday 22 November 2024	D1	Stay in the unit: administration of the study medication
Saturday 23 November 2024	D2	Stay in the unit
Sunday 24 November 2024	D3	Stay in the unit
Monday 25 November 2024	D4	Go home in the morning
Wednesday 27 November 2024	D6	Morning return
Friday 29 November 2024	D8	Morning return (fasted)
Friday 6 December 2024	D15	Morning return (fasted)
Friday 13 December 2024	D22	Morning return (fasted)
Period 2		
Thursday 19 December 2024	D28	Admission to the unit in the afternoon
Friday 20 December 2024	D29	Stay in the unit: administration of the study medication
Saturday 21 December 2024	D30	Stay in the unit
Sunday 22 December 2024	D31	Stay in the unit
Monday 23 December 2024	D32	Go home in the morning
Friday 27 December 2024	D36	Morning return (fasted)
Friday 3 January 2025	D43	Morning return (fasted)
Friday 10 January 2025	D50	Morning return
Period 3		
Thursday 16 January 2025	D56	Admission to the unit in the afternoon
Friday 17 January 2025	D57	Stay in the unit: administration of the study medication
Saturday 18 January 2025	D58	Stay in the unit
Sunday 19 January 2025	D59	Stay in the unit
Monday 20 January 2025	D60	Go home in the morning
Friday 24 January 2025	D64	Morning return (fasted)
Friday 31 January 2025	D71	Morning return (fasted)
Friday 7 February 2025	D78	Morning return
Friday 14 February 2025	D85	Morning return (fasted)
Friday 28 February 2025	D99	Morning return
Friday 7 March 2025	D106	Morning return
End of trial visit		
Tuesday 18 March 2025	EOS	Standard screening visit (fasted)