Revision: 3.0 dd 15OCT2024

STUDY NUMBER: BE-80-2300368

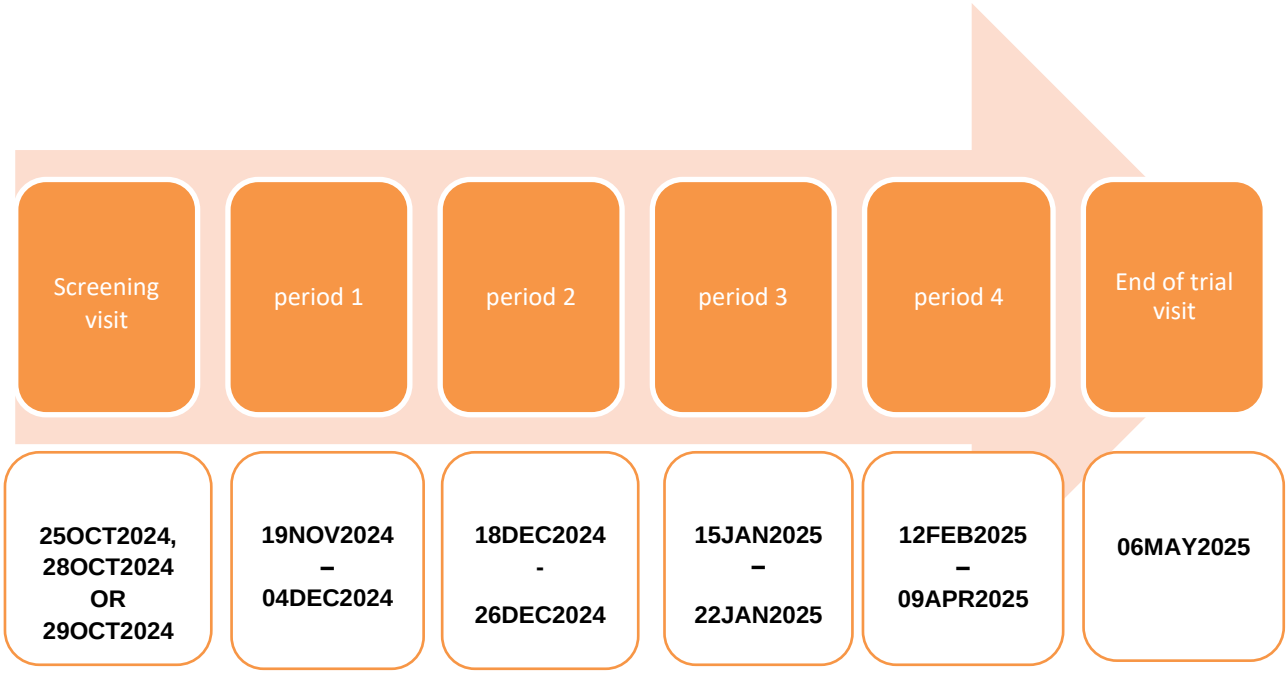
STUDY FOR THE TREATMENT OF FATTY LIVER

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat fatty liver.**

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 **± 28 weeks.**



Study BE-80-2300368 will be conducted in **2 study parts. Part 1 (SRD)** of this study consists of 7 dose groups of 2 sub cohorts each, sentinel (2 volunteers) and main (6 volunteers).

Part 2 (MRD) consists of **5 dose groups** with 10 volunteers per group. You can find the details further in this information sheet. If you are interested, you can certainly indicate your preferred group. Ultimately, you can only participate in one group. This letter only contains information about **part 1 MRD DG11.**

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*):**
  - **DG 11: 21OCT2024**

**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 65 years (**inclusive**)
- BMI: between 18.5 and 30 kg/m²
- Non-smoker or stopped smoking at least 6 months before the screening visit (including nicotine or tobacco containing products, e.g. snuff and chewing tobacco, cigars, cigarettes, electronic cigarettes, pipes, or nicotine patches)
- No use of medication, vitamins, or homeopathic products (it could be possible that the use of specific medication is allowed during the study, but this must be first discussed with the doctor)
- Contraception:
  - **Females of childbearing potential:**
    - **OR** postmenopausal (= 24 months without menstruation)
    - **OR** hysterectomy (= removal of uterus)
    - **OR** bilateral salpingectomy (= removal of both fallopian tubes)
    - **OR** bilateral oophorectomy (= removal of both ovaries)
  - **Men** from administration of the study medication up to and including the final examination.
    - **If you have a fertile (female) partner:**
      - **OR** using a condom
      - **OR** abstinence
- During the study you will be asked to adhere to restrictions regarding physical activity, consumption of grapefruit (juice) and other fruit juices, caffeinated and alcoholic products
- No blood donations (> 100ml) 30 days before administration of the study medication, as well as during the entire study
- **Your profile is not eligible if you:**
  - Central nervous system disorders (including, but not limited to, any form of seizure or stroke) and other relevant neurological or psychiatric disorders
  - History of relevant orthostatic hypotension (low blood pressure upon standing), fainting or blackouts
  - History of relevant chronic or acute infections (e.g. hepatitis B, C and HIV infections)
  - Active or latent (infected but without symptoms) tuberculosis Documented active (or suspected) malignant cancer or history in the past 5 years prior to screening
  - History of relevant allergy or hypersensitivity (including allergy to study medication and derivatives)
  - Consumes an average of 1 unit of alcohol (women) and 2 units of alcohol (men) per day
  - History of additional risk factors for Torsade de Pointes (e.g. heart failure, hypokalemia (too little potassium) or family history of long QT syndrome)
  - Have been an effective volunteer (and thus have received the study medication) in study **BE-80-2100805** and/or study **BE-80-2300065**

COURSE OF THE STUDY

DG11		
Screening		
Friday 25 October 2024 **OF** Monday 28 October 2024 **OF** Tuesday 29 October 2024	Screening	Standard screening visit (fasted) +/-3h
Period 1		
Tuesday 19 November 2024	D-1	Morning return (fasted) Admission to the unit in the afternoon
Wednesday 20 November **2024**	**D1**	**Stay in the unit:** **administration of the study medication**
Thursday 21 November 2024	D2	Going home in the morning
Friday 22 November 2024	D3	Follow-up: phone call
Sunday 24 November 2024	D5	Visit to the unit without overnight stay
Wednesday 27 November 2024	D8	Visit the unit without an overnight stay (fasted)
Wednesday 4 December 2024	D15	Visit the unit without an overnight stay (fasted)
Period 2		
Wednesday 18 December 2024	**D29**	**Day stay without overnight stay:** **administration of the study medication (fasted)**
Thursday 26 December 2024	D36	Visit the unit without an overnight stay (fasted)
Period 3		
Wednesday 15 January 2025	**D57**	**Day stay without overnight stay:** **administration of the study medication (fasted)**
Wednesday 22 January 2025	D64	Visit the unit without an overnight stay (fasted)
Period 4		
Wednesday 12 February 2025	**D85**	**Day stay without overnight stay:** **administration of the study medication (fasted)**
Thursday 13 February 2025	D86	Return visit
Friday 14 February 2025	D87	Follow up: phone call
Sunday 16 February 2025	D89	Visit to the unit without overnight stay
Wednesday 19 February 2025	D92	Visit the unit without an overnight stay (fasted)
Wednesday 26 February 2025	D99	Visit the unit without an overnight stay (fasted)
Wednesday 12 March 2025	D113	Visit the unit without an overnight stay (fasted)
Wednesday 9 April 2025	D141	Visit the unit without an overnight stay (fasted)
End of trial visit		
Tuesday 6 May 2025	D168	Standard examination (fasted) +/- 3h

REMUNERATION* FOR YOUR ENGAGEMENT

- **€ 2000** for completing the entire study (including selection visit)
- **€ 400** for reserve volunteers (including selection visit)
- **€ 50** for the selection visit

**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-80-2300368**
DG11

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 call you as soon as possible.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300368

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