

**STUDY MEDICATION FOR THE TREATMENT OF PRIMARY IMMUNE THROMBOCYTOPENIA****SGS – Clinical Research**

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Edegem, 21 December 2022

**Study number: BE-80-2100607**

Dear

We are currently looking for healthy volunteers to participate in a trial with **study medication for the treatment of primary immune thrombocytopenia** (= the body breaks down the platelets too quickly).

The study consists of 36 subjects divided into several cohorts. You can subscribe for multiple cohorts, but you can only participate in 1. The study will take about 18 weeks to complete.

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

The study consists of:

- A standard screening visit
- 2 periods each consisting of 14 or 15 morning returns (short visit to our Unit) and a stay of 5 days and 4 nights in our unit
- An end of trial visit

If you introduce a family member or acquaintance not yet registered in our database and participates in a selection visit, SGS will provide you with a voucher of **€ 50**. Please follow up whether you are entitled to a voucher which can only be collected in the offices of the recruitment team.

Kind regards,

The SGS recruitment team

## INCLUSION CRITERIA

- Healthy men
- Age: between 18 and 50 years (both inclusive)
- BMI: between 18.5 and 30.0 kg/m<sup>2</sup> (both inclusive)
- Weight between 50 and 100 kg (both inclusive)
- Non-smoker (including e-cigarettes) or ex-smoker
- Not using any medication, vitamin or homeopathic substances
- **Latest participation (last medication intake) in a clinical trial:**
  - **Cohort C2: 28DEC2022**
  - **Cohort C3: 16JAN2023**
- Contraception:
  - **OR** double barrier = consisting of a male condom and contraception for a female fertile partner
  - **OR** using a condom with an infertile female partner
  - **OR** vasectomized men should also use a condom
  - **OR** abstinence
- Willing to not donate sperm (from the first dose up to and including 90 days after the last dose)
- You must not have a history of platelet problems
- You must not have a history of blood clots, heart attack, pulmonary embolism (a clot in the pulmonary veins), ...
- You must not have a history of cancer in the past 5 years
- In the past year you have had none of the following: vitamin B12/folic acid/iron deficiency, major bleeding, depression requiring treatment with medication, migraine requiring monthly medication, gout, diagnosis of eczema
- You must not have had major surgery 3 months before screening
- You must not have taken corticosteroids in the last 3 months before screening
- You must not have a history of hepatitis B and/or C
- Willing to not donate blood 2 months before screening
- You must have suitable veins for multiple venipunctures
- You must not have a history of drug or alcohol abuse within 1 year of screening
- Willing to consume no more than 7 units of alcohol per week
- COVID-19 vaccine allowed 14 days before first dosage and 28 days after last study medication
- You have not participated in a previous cohort of this trial.
- Participation of CPU staff or Sponsor staff:
  - You are no (direct *family of a*) staff member of the sponsor (Gedeon Richter)
  - You are no (direct *family of a*) staff member of SGS CPU

### **TAX-FREE REMUNERATION**

- **€ 5300** for completing the entire study (including selection visit)
- **€ 400** for reserve volunteers (including selection visit)
- **€ 50** for the standard screening visit

Travel reimbursement applies to effective and reserve volunteers and is set at € 0.3542/km, with a maximum of 120 km (one way)

The payment of reserve volunteers starts after D1. Effective volunteers will be paid after completion of the last visit. The payment term will take up to 4-6 weeks.

### **ATTENTION:**

- In the event of early study termination, the financial compensation can be adjusted based on the study duration as well as the reason for early termination. This decision will be taken by the SGS study team.
- You will **not** receive any payment if you test positive for illegal substances or alcohol at the selection visit.

### **ARE YOU A RESERVE VOLUNTEER?**

- You will be admitted to the unit at **D-1** and will stay approximately 2 hours after administration of the study medication on **D1**
- You meet all inclusion criteria and you have kept all study restrictions given at the selection visit
- You are able to participate in the entire study

## **SUBSCRIPTION**

**Do you want to subscribe? Please follow the below steps:**

### **step 1**

Mail now to [be.inschrijvingen@sgs.com](mailto:be.inschrijvingen@sgs.com)

**OR**

Call now to **+32 (0)3 217 21 72**

(please call between 8h-12h and 13h-17h)

**The point of time you subscribed will determinate your sequence during the trial.**

### **step 2**

Please mention the below:

Study number **BE-80-2100607 Cohort C2 and/or cohort C3**

Name and Surname

Date of birth

Phone number

### **step 3**

**If your profile qualifies for the study we will contact you as soon as possible to schedule an appointment for the screening visit.**

Reacting to this letter only expresses your interest and does not oblige you nor us to subscribe (or accept your request) to participate.

**COURSE OF THE STUDY**

<b>Cohort C2</b>		
<b>Screening</b>		
Between Friday 16 December 2022 and Friday 6 January 2023	Screening	Standard screening visit +/- 3u (fasted)
<b>Period 1</b>		
Thursday 26 January 2023	D-1	Morning return (fasted) and come to the unit around 18h
<b>Friday 27 January 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
zaterdag 28 January 2023	D2	Stay in the unit
zondag 29 January 2023	D3	Stay in the unit
Monday 30 January 2023	D4	Go home around 11h
Wednesday 1 February 2023	D6	Morning return +/- 1h
Friday 3 February 2023	D8	Morning return +/- 2h (fasted)
Sunday 5 February 2023	D10	Morning return +/- 1h
Monday 6 February 2023	D11	Morning return +/- 1h
Tuesday 7 February 2023	D12	Morning return +/- 1h
Wednesday 8 February 2023	D13	Morning return +/- 1h
Thursday 9 February 2023	D14	Morning return +/- 2h
Friday 10 February 2023	D15	Morning return +/- 1h
Sunday 12 February 2023	D17	Morning return +/- 1h
Wednesday 15 February 2023	D20	Morning return +/- 1h (fasted)
Sunday 19 February 2023	D24	Morning return +/- 1h
Thursday 23 February 2023	D28	Morning return +/- 1h
Thursday 2 March 2023	D35	Morning return +/- 1h
<b>Period 2</b>		
Thursday 9 March 2023	D-1	Morning return (fasted) and come to the unit around 18h
<b>Friday 10 March 2023</b>	<b>D1</b>	<b>Stay in the unit: administration of the study medication</b>
Saturday 11 March 2023	D2	Verblijf in de unit
Sunday 12 March 2023	D3	Verblijf in de unit
Monday 13 March 2023	D4	Naar huis rond 18u
Wednesday 15 March 2023	D6	Morning return +/- 1h
Friday 17 March 2023	D8	Morning return +/- 2h (fasted)
Sunday 19 March 2023	D10	Morning return +/- 1h
Monday 20 March 2023	D11	Morning return +/- 1h
Tuesday 21 March 2023	D12	Morning return +/- 1h
Wednesday 22 March 2023	D13	Morning return +/- 1h
Thursday 23 March 2023	D14	Morning return +/- 2h
Friday 24 March 2023	D15	Morning return +/- 1h
Sunday 26 March 2023	D17	Morning return +/- 1h
Wednesday 29 March 2023	D20	Morning return +/- 1h (fasted)
Sunday 2 April 2023	D24	Morning return +/- 1h
Thursday 6 April 2023	D28	Morning return +/- 1h
Thursday 13 April 2023	D35	Morning return +/- 1h
<b>End of trial visit</b>		
Thursday 20 April 2023	VD	Standard screening visit +/- 3h (fasted)

<b>Cohort C3</b>		
<b>Screening</b>		
Between Wednesday 4 January 2023 and Wednesday 25 January 2023	Screening	Standard screening visit (fasted) +/- 3h
<b>Period 1</b>		
Tuesday 14 February 2023	D-1	Morning return (fasted) and come the unit in the evening around 18h
<b>Wednesday 15 February 2023</b>	<b>D1</b>	<b>Stay in the unit: Administration of the study medication</b>
Thursday 16 February 2023	D2	Stay in the unit
Friday 17 February 2023	D3	Stay in the unit
Saturday 18 February 2023	D4	Go home around 11h
Monday 20 February 2023	D6	Morning return visit +/- 1h
Wednesday 22 February 2023	D8	Morning return visit +/- 2h (fasted)
Friday 24 February 2023	D10	Morning return visit +/- 1h
Saturday 25 February 2023	D11	Morning return visit +/- 1h
Sunday 26 February 2023	D12	Morning return visit +/- 1h
Monday 27 February 2023	D13	Morning return visit +/- 1h
Tuesday 28 February 2023	D14	Morning return visit +/- 2h
Wednesday 1 March 2023	D15	Morning return visit +/- 1h
Friday 3 March 2023	D17	Morning return visit +/- 1h
Monday 6 March 2023	D20	Morning return visit +/- 1h (fasted)
Friday 10 March 2023	D24	Morning return visit +/- 1h
Tuesday 14 March 2023	D28	Morning return visit +/- 1h
Tuesday 21 March 2023	D35	Morning return visit +/- 1h
<b>Period 2</b>		
Tuesday 28 March 2023	D-1	Morning return (fasted) and come the unit in the evening around 18h
<b>Wednesday 29 March 2023</b>	<b>D1</b>	<b>Stay in the unit Administration of the study medication</b>
Thursday 30 March 2023	D2	Stay in the unit
Friday 31 March 2023	D3	Stay in the unit
Saturday 1 April 2023	D4	Go home around 18h
Monday 3 April 2023	D6	Morning return visit +/- 1h
Wednesday 5 April 2023	D8	Morning return visit +/- 2h (fasted)
Friday 7 April 2023	D10	Morning return visit +/- 1h
Saturday 8 April 2023	D11	Morning return visit +/- 1h
Sunday 9 April 2023	D12	Morning return visit +/- 1h
Monday 10 April 2023	D13	Morning return visit +/- 1h
Tuesday 11 April 2023	D14	Morning return visit +/- 2h
woensdag 12 April 2023	D15	Morning return visit +/- 1h
Friday 14 April 2023	D17	Morning return visit +/- 1h
Monday 17 April 2023	D20	Morning return visit +/- 1h (fasted)
Friday 21 April 2023	D24	Morning return visit +/- 1h
Tuesday 25 April 2023	D28	Morning return visit +/- 1h
Tuesday 2 May 2023	D35	Morning return visit +/- 1h
<b>End of trial visit</b>		
Tuesday 9 May 2023	VD	Standard screening visit (fasted) +/- 3h