

Revision: 1.0 dd 21AUG2025

STUDY NUMBER: BE-80-2400381

## STUDY FOR THE TREATMENT OF AUTOIMMUNE DISEASES

Dear pioneer,

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

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 **± 6 months**.

**Study BE-80-2400381** will be conducted in a maximum of 9 groups. **Group 8** includes **9 participants**. More details can be found further in this information sheet. This letter contains information about group 8. If interested, you can let us know your preferred group. Ultimately, you can only participate in one group.

The study medication will be monitored **subcutaneously** (by injection under the skin in the abdomen).

**Selected as a reserve?** You enter the unit on Day-1 with the possibility of stepping in as an effective participant in case someone drops out last minute. You are available for all study dates and adhere to the study conditions. If you don't need to fill in, you can go home after the dosing of the effective participants.

## INCLUSION CRITERIA

- **Last participation in other clinical trial (last study medication\*):**  
**Group 8.3: not later than 09JUN2025**  
*\*Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men and (infertile) women
- Age: between 18 and 65 years (**inclusive**)
- BMI: between 18 – 30 kg/m<sup>2</sup> (**inclusive**)
  - Weight between 50 and 100 kg
- Non-smoker or stopped smoking minimum 3 months before screening visit (including nicotine-containing products such as e-cigarettes, nicotine patches, etc.)
- Not using any medication, vitamins or homeopathic substances (in consultation with the physician, it may be possible to continue taking certain medications during the study)
- Contraception:
  - **Men:** (from screening until 15 months after the last administration of the study medication)
    - Use of a condom if your female partner is of childbearing potential
    - **OR** abstinent
  - **Infertile women:**
    - **OR** postmenopausal (no menses for at least 12 months)
    - **OR** removal of the uterus
    - **OR** removal of both fallopian tubes
    - **OR** removal of both ovaries

- **Prepared to:**
  - Men: not donate sperm from the administration of the study medication until 15 months after the administration of the study medication
- **Your profile is not eligible if you:**
  - Have an autoimmune disease
  - have donated or lost blood (due to an operation, accident, etc.) in the 12 weeks before the first administration of the study medication
  - Have undergone major surgery 3 months before screening or if this is planned during the study
  - Received a vaccine 4 weeks before screening
  - Have an acute or chronic infection of hepatitis B or C, or HIV
  - Are an employee (or family member) of the sponsor Argenx or SGS CPU who is directly involved in the study

#### **REMUNERATION\* FOR YOUR ENGAGEMENT**

- **€ 3300** for completing the entire study (including screening visit)
- **€ 400** for reserve volunteers (including screening visit)
- **€ 50** for the screening visit

*\*Tax-free in Belgium. In addition, you will receive reimbursement for your travel expenses, which is set at € 0,4290 per km, with a maximum of 120 km (one way).*

Payment of those who are screen failures & reserves will be started after dosing. 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.*

Thank you in advance for your interest and we hope to welcome you soon for study **BE-80-2400381**.

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