

STUDY NUMBER: 2500059 PART 1

Dear pioneer,

A study to **treat atopic dermatitis** will soon start at our research centre in Edegem.

Are you interested in participating and giving science a boost?

Hereby we would like to give you an overview of the study: duration of **± 14 weeks**.

In this cohort, the study medication will be administered subcutaneously (under the skin).

INCLUSION CRITERIA

- **Last participation in other clinical study (last study medication*):**
Part 1 Cohort 6 sentinel: no later than 17MAY2026
**Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men and/or women **between** 18 and 55 years of age (inclusive at screening)
- BMI: between 18.0 and 30.0 kg-m² (inclusive at screening)
 - Weight between 45.0 and 100.0 kg
- Non-smoker or smoking maximum 10 cigarettes or equivalents **per week** (Please note that smoking is not permitted during the study.)
- 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). Hormone replacement therapy for menopause is permitted.
- Contraception:
 - Fertile women: *from day 1 and until at least 16 weeks after the last administration of study medication*
 - Be prepared to use an effective method of contraception (the pill, intra uterine device, contraceptive injection, patch, partner vasectomy, etc.)
 - **OR** Abstinence
 - **AND** Be prepared not to donate eggs
 - Infertile women: *from day 1 and until at least 16 weeks after the last administration of study medication*
 - postmenopausal (= no menstruation for at least 12 months)
 - **OR** removal of uterus
 - **OR** removal of both ovaries
 - **OR** removal of both fallopian tubes
 - Men: *from day 1 and until at least 16 weeks after the administration of study medication*
 - A male condom when engaging in any activity that allows for passage of ejaculate to another person
 - If you have a fertile partner: use of condoms + advice on the use of an effective method of contraception by the partner.
 - **OR** Abstinence
 - **AND** Refrain from donating sperm.
- You will be asked to follow the restriction regarding physical activity, consumption of xanthine or caffeine-containing products (eg. coffee, tea, cola drinks and chocolate) and alcoholic products.
- You are not (*family of*) an employee of SGS, who is directly involved in the study.
- You are not eligible if:
 - You have a history of active or latent tuberculosis (TBC)
 - You have atopic eczema
 - You have frequent headaches and/or migraine, recurrent nausea and/or vomiting (> twice a month)
 - You had an active infection within 3 weeks before the start of the study

- You donated blood (500ML) less than 1 month before administration of the study medication.
- You participated in another study involving biological medicines less than 4 months prior to receiving the study medication.
- You have received a non-live vaccine (e.g., flu, whooping cough, hepatitis A, etc.) less than 4 weeks before the administration of the study medication.
- You have been given a live vaccine (e.g., measles, polio, mumps, etc.) less than 3 months before receiving the study medication.
- You participated in a previous cohort of this study.

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 2500059 part 1.

SGS CPU