

STUDY NUMBER: 2500305

Dear pioneer,

A study to **treat auto-immune diseases** 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 **± 9 weeks**.

In this cohort, the study medication will be administered **orally (via the mouth)**.

INCLUSION CRITERIA

- **Last participation in other clinical study (last study medication*):**
Part 5 no later than: **03OKT2026 (30days before screening)**
**Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men and women **between the age of 18 and 60 years (including)**
- BMI: **18.0-30.0 kg/m² (including)**
 - Weight minimum: **50.0 kg**
- Non-smoker or stopped smoking minimum **6 months before the day of screening** (including e-cigarettes, nicotinepatches,...)
- 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:
 - Fertile women: from first dose up to and including 90 days after last administration of study medication:
 - The use of an effective method of contraception (e.g. the pill, spiral, vaginal ring...) if the partner is a fertile man
 - **OR** abstinence from heterosexual intercourse
 - **OR** male partner infertile
 - **AND** no egg donation
 - Infertile women:
 - postmenopausal (= no menstruation for at least 12 months)
 - **OR** removal of uterus
 - **OR** removal of both ovaries
 - **OR** removal of both fallopian tubes
 - **OR** congenital abnormalities leading to sterility
 - Men: from first dose up to and including 90 days after last administration of study medication:
 - Using a condom
 - **OR** abstinence
 - **AND** no sperm donation
- You will be asked to follow the restriction regarding physical activity, consumption of grapefruit (juice), caffeine- and alcoholic products.
- You are not (*family of*) an employee of the sponsor "**Janssen research & Development**" OR not (*family of*) an employee of SGS, who is directly involved in the study.
- You are willing to eat a high fat, high calorie breakfast 2 times during the study.
- No blood donations (500ml of more) 3 months before the screening or planned during the study
- You have not had an operation in the 12 weeks prior to screening.

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.



Pre-recruitment Information Sheet_EN
Referenced Controlled Document

Thank you in advance for your interest and we hope to welcome you soon for study 2500305.

SGS CPU