

STUDY NUMBER: 2500291 PART B

Dear pioneer,

A study to **treat acute alcohol-related liver inflammation** 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 **± 20 weeks**.

In this group, the study medication will be administered **intravenously**.

INCLUSION CRITERIA

- **Last participation in other clinical study (last study medication*):**
Part B DG33 not later than: **17AUG2026** (60 days before administration)
**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 **between** age of 18 and 65 year (inclusive)
- BMI: **18.5 – 30.0 kg/m² (inclusive)**
- Smoker, non-smoker or ex-smoker **(smoking is not permitted in the unit during your stay!)**
- Not using any medication, vitamins, or homeopathic substances
- Contraception:
 - Infertile women: **Hormone replacement therapy is permitted**
 - 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 dosage up to and including the final examination)
 - Condoms or abstinence if the partner is fertile.
- You will be asked to adhere to the restrictions regarding physical activity and alcohol consumption.
- No prior participation in any of the preceding groups/cohorts of this study.
- No history of cancer within 5 years of screening.
- No central nervous system diseases (including but not limited to seizures or strokes of any kind) or other relevant neurological or psychiatric conditions.
- No history of hepatitis B, hepatitis C, tuberculosis, or HIV.
- No blood donation of more than 100 ml within 30 days of receiving study medication or planned blood donations during the 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 2500291.

SGS CPU