

## 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 DG11** not later than: **12JUL2026** (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/m<sup>2</sup> (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**