

STUDY NUMBER: 2500577 PART A

Dear pioneer,

A study to **treat hepatitis E infections** 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 **± 5 weeks**.

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

INCLUSION CRITERIA

- **Last participation in other clinical study (final study visit*):** *not later than 12 weeks before the first administration of the study medication*
 - **cohort 1a main:** not later than **07MAY2026**
**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 age of 18 en 65 years (inclusive) at screening
- BMI: 18.0 – 29.0 kg/m² (inclusive) at screening
 - Weight at least 50.0 kg at screening
- Non-smoker or stopped smoking at least 6 months prior to day -1 (including e-cigarettes, nicotine patches, snuff, nicotine gum, 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:
 - **Fertile women:** *from screening until at least 30 days after administration of the study medication*
 - Be willing to use an effective contraceptive method (the pill, IUD, contraceptive injection, patch, partner's vasectomy, etc.) in combination with an effective barrier method such as the male condom.
 - **OR** abstinence
 - **AND** be prepared not to donate eggs.
 - **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
 - **Men:** *from screening and until at least 90 days after the administration of the study medication*
 - If your partner is fertile: use a condom + use of an effective method of contraception by your partner
 - **OR** vasectomy
 - **OR** abstinence
 - **AND** be prepared not to donate sperm
- Willing to wear a holter monitor during the stay in the unit.
- You will be asked to follow the restrictions regarding physical activity, consumption of grapefruit (juice), poppy seeds, caffeine, xanthine and alcoholic products.



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 2500577 part A.

SGS CPU