

## **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 4a main:** not later than **26JUN2026**  
*\*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/m<sup>2</sup> (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 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.
- You are not eligible if you participated in a previous cohort of study 2500577.



### **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**