STUDY NUMBER: 2400067 PART 2

Dear pioneer,

A study to **treat gonorrhea** 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 **± 6 weeks.**

In this group the study medication will be **orally** (liquid solution) administered.

INCLUSION CRITERIA

- **Last participation in other clinical study (last study medication):**
  - Cohort 4 sentinel not later than: **24JUN2026**

  **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** 18 and 55 years (inclusive)
- between 18.5 and 30.0 kg/m² (inclusive)
- Non-smoker or stopped smoking minimum 6 months before administration of the study medication (including, e-cigarettes, nicotine or nicotine-containing products)
- 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 41 days after administration of the last study medication)
    - Use of an effective method of contraception (e.g. (copper) coil) **– systemic hormonal contraception (the pill, patch, implant and injection) is not permitted**
    - **abstinence**
  - Infertile women: **hormone replacement therapy is not allowed**
    - 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 administration of the study medication until 101 days after last administration of the study medication)
    - abstinence from any form of sexual intercourse as a lifestyle
    - OR use of a condom (also in case of sterilization)
      - in combination with an effective method of contraception if your female partner is fertile

- You will be asked to follow the restriction regarding physical activity, consumption of Seville oranges, grapefruit (juice), caffeine- and alcoholic products.
- No previous participation in any of the previous cohorts of this study
- **You are not eligible if you**
  - have donated or lost blood (due to surgery, accident, transfusion, etc.) in the 12 weeks prior to the screening
  - have relevant cardiovascular, respiratory, renal, hepatic, neurological, gastrointestinal, metabolic, immunological, psychiatric or mental disorders
  - have had a relevant procedure or condition of the gastrointestinal tract/digestive system (e.g.: gastric reduction, removal of a piece of intestine, removal of the gallbladder, removal of the appendix is not a problem)
  - have a history of HIV and hepatitis B and C

- **It is not permitted to:**
  - donate sperm from the administration of the study medication until 101 days after the administration of the study medication
  - donate eggs from the administration of the study medication until 41 days after the administration of the study medication

- Participation of CPU employees or Sponsor employees:
  - You are not (family of) an employee of the sponsor Debio or SGS, who is directly involved in 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 2400067 part 2.

SGS CPU