STUDY NUMBER: 2600008

Dear pioneer,

A study **evaluating a new way of administering medication through the inside of the cheek** 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 **± 13 weeks**.

In this cohort, the study medication will be administered **buccally (through the oral mucosa).**

INCLUSION CRITERIA

- **Last participation in other clinical study (last study medication*):**
  - **Cohort D sentinel:** no later than **18DEC2026**

  **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)
- BMI between 18.0 and 30.0 kg/m²
  - Weight at least 50.0 kg
- Non-smoker or stopped smoking at least 6 months before administration of the study medication
  - including nicotine-containing products such as e-cigarettes, nicotine patches and gum, chewing tobacco, etc.
- Not using any medication, vitamins, or homeopathic substances
  - oral contraception is allowed for fertile women and hormone replacement therapy for women in menopause
- Contraception:
  - **Fertile women: until 16 weeks after administration of the study medication**
    - **If male partner is fertile:**
      The use of an effective contraceptive method (e.g., IUD, vaginal ring…)
      - If you are taking oral contraceptives, you need to use them in combination with a condom
    - **OR** abstinence
    - No egg donations (or freezing)
  - **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: until 90 days after administration of the study medication**
    - **If female partner is fertile:**
      The use of a condom in combination with an effective method of contraception is mandatory
    - **OR** vasectomy
    - **OR** abstinence
    - No sperm donations (or freezing)
- No blood donations or blood loss (> 500mL) 3 months before administration of the study medication
- You will be asked to follow the restrictions regarding physical activity, consumption of grapefruit (juice), caffeine- and alcoholic products
- You are not *(family of)* an employee of SGS, who is directly involved in the study

- **Your profile does not qualify for the study if you:**
  - have a condition or abnormality in the oral cavity that affects the oral mucosa
  - have a tongue or cheek piercing
  - suffer from dry mouth or have suffered from this in the past
  - had major surgery (under general anesthesia) scheduled or performed within 12 months prior to the screening visit (excluding local anesthesia)
  - had severe allergic reactions to food or medication (e.g., angioedema or anaphylactic shock)
  - had symptomatic shingles in the 3 months prior to the screening visit
  - had a serious infection in the 4 months prior to the screening visit, that required hospitalization **OR** for which intravenous antibiotics were administered
  - have a known history of or currently suffer from tuberculosis
  - are difficult to puncture

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 2600008.

SGS CPU