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STUDY NUMBER: BE-80-2300376

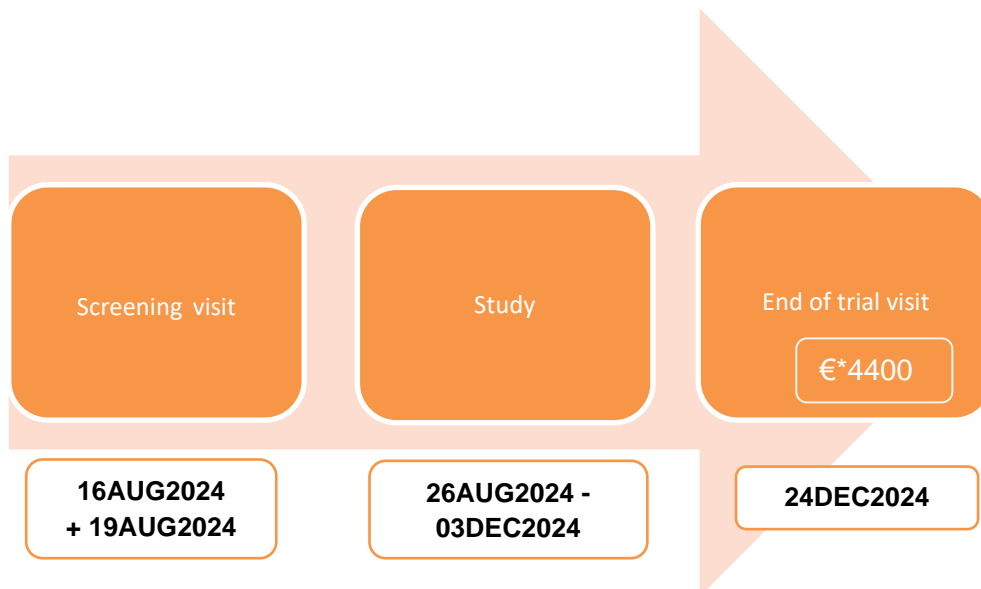
STUDY FOR THE TREATMENT OF ASTHMA, CHRONIC SINUSITIS AND ECZEMA

Dear pioneer,

Soon, a study will start at our research centre in Edegem to **treat asthma, chronic sinusitis, and eczema.**

Are you interested in participating and giving science a boost?

We hereby would like to provide you with an overview of the study: duration of **± 21 weeks.**



* Fixed fee. In addition, you will receive reimbursement for your travel expenses, which is set at € 0,3542 per km, with a maximum of 120 km (one way).

Study BE-80-2300376 will be conducted in **2 study parts. Part 2 of this study consists of a maximum of 2 cohorts of 10 people each.** This letter contains information about part 2 cohort 1 of which you can find the details further in this recruitment letter. You can subscribe for multiple cohorts, but only participate in 1 cohort. If interested, you can let us know your preferred cohort and ultimately you can only participate in one cohort.

Selected as a reserve? Then you will enter the unit and you may go home when everyone is dosed. If someone drops out, you are able to participate in the full study and take that person's place. During the period, you adhere to the study requirements.

INCLUSION CRITERIA

- **Last participation in other clinical trial (last study medication*):**
 - **MAD cohort 2: not later than 29MAR2024**
**Be careful: Final study visit of the previous study needs to be performed to be able to participate at screening.*
- Healthy men and women
- Age: between 18 and 55 years old (**inclusive**)
- BMI: between 18.5 – 30.0 kg/m² (**inclusive**)
 - Men: weight between 50.0 and 100.0 kg (**inclusive**)
 - Women: weight between 40.0 kg and 90.0 kg (**inclusive**)
- Non-smoker or smoking maximum 5 cigarettes per week (inclusive nicotine patch and E-cigarettes)
 - **It is not allowed to smoke during the entire study**
- No use of medication, vitamins or homeopathic products (it could be possible that the use of specific medication is allowed during the study, but this must be first discussed with the doctor)
- Contraception:
 - Females of childbearing potential:
 - Use of an effective contraception method (f.e oral contraception, intrauterine device, vaginal ring, ...) during the entire study until at least 3 months after the last administration of the study medication. When using hormonal contraception, a condom must also be used in the male partner.
 - Females of non-childbearing potential:
 - **OR** postmenopausal (no menses for at least 12 months)
 - **OR** hysterectomy (removal of the uterus)
 - **OR** bilateral salpingectomy (removal of both fallopian tubes)
 - **OR** bilateral ovariectomy (removal of both ovaries)
 - **OR** permanently infertile (due to an alternative medical cause)
 - Men (during the entire study until at least 3 months after the last administration of the study medication)
 - **OR** abstinence from heterosexual intercourse as their preferred and usual lifestyle
 - **OR** use of a condom
 - in combination with a reliable contraception method (for the female partner of childbearing potential)
- Prepared to:
 - not donate sperm (men) or eggs (women) during the entire study until at least 3 months after the last administration of the study medication
 - not consume alcohol for 24 hours before admission until discharge.
 - At all other timepoints, alcohol use should remain within the recommended limits of 14 units per week
 - not do any intensive physical activity for the duration of the study until the end of study visit
 - not consume St John's Wort or ginseng containing products from 14 days before admission
 - consume a maximum of 4 units of caffeine per day (including coffee, tea, cola, chocolate) during the entire study
- Participation of CPU employees or Sponsor employee:
 - You are not (family of) an employee of SGS or the sponsor Sanofi, who is directly involved in the study.

- **You are not eligible if you:**
 - have any history or presence of clinically relevant cardiovascular, pulmonary, gastrointestinal, hepatic, renal, metabolic, hematological, neurological, dermatological, osteomuscular, articular, psychiatric, systemic, ocular, gynecologic (if female), or infectious disease, or signs of acute illness.
 - have donated or lost blood or plasma (due to an operation, accident, ...) within 8 weeks before inclusion
 - have frequent headaches and/or migraine, recurrent nausea and/or vomiting (for vomiting only: more than twice a month)
 - have skin burns, scars or large tattoos on the abdomen
 - will receive a non-live vaccine (including COVID-19 vaccine) 7 days before the first administration of the study medication
 - have received a live vaccine 4 weeks before administration of the study medication or are planning to have a vaccine administered during the study

REMUNERATION * FOR YOUR ENGAGEMENT

- € 4400 for completing the entire study (including selection visit)
- € 400 for reserve volunteers (including selection visit)
- € 50 for the selection visit (Travel reimbursement excluded*)

**Tax-free in Belgium*

Payment of those who are screen failures & reserves will be started after dosing. When you are effectively a study participant, payment will start after your final study. The pay-out period will take \pm 4 to 6 weeks.

In case of early termination of the study, this payment can be adjusted based on the final study duration as well as based on the reason for early termination. This decision will be made jointly by the SGS study team.

COURSE OF THE STUDY

MAD Cohort 2		
Screening		
Friday August 16, 2024 OR Monday August 19, 2024	Screening	Standard examination (fasted) +/- 3h
Study		
Monday August 26, 2024	D-1	Morning return (fasted) +/- 1h and evening admission around 18h
Tuesday August 27, 2024	D1	Stay in the unit: administration of the study medication
Wednesday August 28, 2024	D2	Stay in the unit
Thursday August 29, 2024	D3	Stay in the unit
Friday August 30, 2024	D4	Go home in the morning around 11h
Saturday August 31, 2024	D5	Morning return (not fasted) +/- 1h
Sunday September 1, 2024	D6	Morning return (not fasted) +/- 1h
Tuesday September 3, 2024	D8	Morning return (not fasted) +/- 1h
Monday September 9, 2024	D14	Morning return (fasted) +/- 1h and evening admission around 18h
Tuesday September 10, 2024	D15	Stay in the unit: administration of the study medication
Wednesday September 11, 2024	D16	Stay in the unit
Thursday September 12, 2024	D17	Stay in the unit
Friday September 13, 2024	D18	Go home in the morning around 11h
Sunday September 15, 2024	D20	Morning return (not fasted) +/- 1h
Tuesday September 17, 2024	D22	Morning return (not fasted) +/- 1h
Monday September 23, 2024	D28	Morning return (fasted) +/- 1h and evening admission around 18h
Tuesday September 24, 2024	D29	Stay in the unit: administration of the study medication
Wednesday September 25, 2024	D30	Stay in the unit
Thursday September 26, 2024	D31	Stay in the unit
Friday September 27, 2024	D32	Stay in the unit
Sunday September 28, 2024	D33	Go home in the morning around 11h
Wednesday September 29, 2024	D34	Morning return (not fasted) +/- 1h
Tuesday October 1, 2024	D36	Morning return (not fasted) +/- 1h
Tuesday October 8, 2024	D43	Morning return (not fasted) +/- 1h
Tuesday October 22, 2024	D57	Morning return (fasted) +/- 1h
Tuesday November 5, 2024	D71	Morning return (not fasted) +/- 1h
Tuesday November 19, 2024	D85	Morning return (fasted) +/- 1h
Tuesday December 3, 2024	D99	Morning return (not fasted) +/- 1h
End of trial visit		
Tuesday december 24, 2024	VD	Standard examination (fasted) +/- 3h

INTEREST IN PARTICIPATING

Registration for this study only indicates your interest and does not obligate you or us to participate.

Registration can be done from **NOW** by emailing the information below to pionier@sgs.com or calling the number **+32 (0)3 217 21 72** (between 8h30-12h and 13h-17h):

Study number: BE-80-2300376
MAD Cohort 2

Last name and first name: ...
Date of birth: ...
Telephone number: ...

The time of your registration determines the order of further processing of your profile for this study.

From **NOW** we will call the **10** first registrations between 8h30 and 17h.

Thank you in advance for your interest and we hope to welcome you soon for study BE-80-2300376

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