

Version 1.0 dd. 23FEB2024

**STUDY MEDICATION IN DEVELOPMENT FOR TREATMENT OF SLEEP
DISTURBANCES ASSOCIATED WITH MENOPAUSE**

SGS – Clinical Research
Clinical Pharmacology Unit
UZA – SGS - Gebouw J
Drie Eikenstraat 655
B-2650 Edegem
03 217 21 72
be.recruiting@sgs.com

Study number: BE-80-2300342

Dear

We are looking for patients for a study with study medication in development for the **treatment of sleep disturbances associated with the menopause.**

The trial runs over a period of \pm 23 weeks.

The trial contains:

- A screening visit 1
- A screening visit 2 including an in house stay of 2 days and 2 nights in the Multidisciplinary Sleepcenter of UZA
- 2 periods including an in house stay of 2 days and 2 nights in the Multidisciplinary Sleepcenter of UZA
- 1 ambulatory visit between period 1 and 2
- 1 phone follow-up visit after period 2
- Daily intake of study medication for 12 weeks, both at home and during the in house stays in the Multidisciplinary Sleepcenter of UZA

If you refer a family member or friend who is not yet part of our database and has participated in a screening visit, SGS will offer you a voucher worth of **€ 50**. Please follow up yourself if you have a right to this voucher. This voucher can only be picked up at the recruitment team.

With kind regards,

The SGS recruitment team

ADMISSION REQUIREMENTS

- Females
- Age: 40 - 65 years
- BMI: 18 – 38 kg/m²
- You are in the post-menopausal period **and** a hysterectomy was performed \geq 6 weeks before screening visit 1.
- You experience hot flashes related to the menopause.
- You suffer from sleep disturbances associated with the menopause (waking up at night and/or poor quality of sleep), with a negative impact on your daily functioning.
- Your time in bed is between 6 and 9 hours and your bedtime is usually between 21.00 and 24.00 hours, with a variation of less than +/- 2 hours.
- You do not take > 3 naps of > 30 minutes per week.
- Besides your sleep disturbances, you are in good general health (no organ diseases, (history of) any malignancy, sleep apnea or other diagnosed sleep disorders).
- You are not taking any chronic medication, or you are willing to stop taking this medication (including hormonal therapy).
 - Occasionally use of anti-allergic medication, nasal sprays of paracetamol is allowed.
- You are not following cognitive behavioral therapy for sleep disorders.
- No excessive use of caffeine, alcohol or drugs.
- Smoking is not permitted in the Clinical Pharmacology Unit of SGS and the Multidisciplinary Sleepcenter of UZA.
- **Last participation in another clinical trial (end of trial visit): 2 months before screening visit 1**
- You are willing to:
 - Complete an electronic diary daily.
 - Take study medication at home daily.
 - Not plan shift work from 2 weeks before screening visit 2 until the end of the study.
 - Not travel across \geq 3 time zones from 2 weeks before screening visit 2 until the end of the study.
- Participation of SGS CPU employees or Sponsor collaborators:
 - You are no employee of SGS CPU or the Sponsor 'Bayer' and you are no family of an SGS CPU employee or the Sponsor 'Bayer'.

Do you know someone who also suffers from these complaints and might be interested in participating in this study? Don't hesitate to share this recruitment letter with her.

TAX FREE COMPENSATION

You will receive a maximum reimbursement of **€ 1206** after completion of all study visits. Compensation will be done by using vouchers and will include the following expenses:

- The Sponsor will reimburse your travel costs (including parking) for € 40 in total per study-specific visit to the hospital or study center for the duration of the study.
- You will receive an additional compensation of € 10 to cover your visit to the hospital or study center (including meals, drinks, ...) for screening visit 1 and all other study-specific visits without overnight stays for the duration of the study.
- You will receive a compensation of € 120 per study-specific overnight stay for your time, effort and inconvenience for the duration of the study.
- You will receive an additional compensation of € 24 for your time and effort for the completion of the diaries at each of the 4 study visits to the hospital or study center, starting from screening visit 2.

REGISTRATION

Would you like to register?

➤ **STEP 1**

Send **from now on** an e-mail to:

pionier@sgs.com

OR

Call **from now on** to:

+32 (0)3 217 21 72

(Calling is only possible between 08:00h – 12:00h
and 13:00h-17:00h)

➤ **STEP 2**

Please mention the following information:

- Study number: BE-80-2300342
- First and last name
- Birth date
- Telephone number

➤ **STEP 3**

If your profile matches the criteria, we will contact you as soon as possible to schedule a screening visit

Your reaction to this letter merely indicates your interest and does not obligate you nor us to registration or (acceptance of your request to) participation.

STUDY COURSE

| STUD DATES | | | |
|-------------------------|-----------------|---------------------------------|-----------------------|
| Screening 1 | | | |
| D-42 | Screening | General investigation (+/- 3h) | |
| Screening 2 | | | |
| D-14 | Screening | Sleep assessment | Arrive around 14h |
| D-13 | | | |
| D-12 | | | Going home around 12h |
| Study | | | |
| D1 | Baseline | Start medication (+/-3h) | |
| D29 | T1 | Sleep assessment | Arrive around 14h |
| D30 | | | |
| D31 | | | Going home around 12h |
| D57 | T2 | General assessment (+/- 3h) | |
| D85 | T3 | Sleep assessment | Arrive around 14h |
| D86 | | | |
| D87 | | | Going home around 12h |
| Follow Up period | | | |
| D113 | FU | Telephone visit | |