CPU525 – Psoriasis

We are looking for healthy male/female volunteers aged between 18 and 60 years (inclusive) to participate in a study with study medication for the treatment of psoriasis.

This study will consist of 2 parts. In Part 1, a single dose of JNJ-77242113 will be administered four times as an oral tablet, each time in a different formulation and/or condition. In Part 2, only the acceptability (taste and smell) of JNJ-77242113 in different oral formulations will be assessed. You will only be invited to participate in Part 1.

You are only eligible if you are currently not participating in any other study, either at Janssen CPU or at another research center. This will be verified using an international database, Verified Clinical Trials (VCT). Have you been invited for a screening? Be sure to bring your identification and adhere to the screening appointments.

Study title

A Phase 1 Study in Healthy Adult Participants Consisting of Two Parts: Part 1 An Open-label, Randomized, Crossover, Multipart Study to Assess the Relative Oral Bioavailability, and Food and Liquid Effect of a JNJ-77242113 Tablet Formulation; Part 2 A Single-blind, Randomized Study to Assess the Acceptability Profile of Different JNJ-77242113 Oral Formulations

Study objectives

Primary:

- Assess the relative oral bioavailability of JNJ-77242113 when administered as a new (IR AbE) tablet formulation compared to a reference tablet formulation in healthy adult participants
- Investigate the effect of food intake on the oral bioavailability and the pharmacokinetic (PK) profile of JNJ-77242113 when administered as this new tablet formulation in healthy adult participants

Secondary:

- Investigate the safety and tolerability of JNJ-77242113 after the administration of oral doses under different food conditions in healthy adult participants

Study process

After formal approval by the Ethics Committee, Janssen CPU conducts the study from May 29, 2024, to June 3, 2025. Part 1 of the study consists of 8 (optional) groups with 8 participants per group.

The following visits will take place:

1. **First visit - screening visit:**
   You will read the informed consent form (ICF). Following this, there will be a discussion with a physician, and you will have the opportunity to ask questions. If you wish to participate in the study, both you and the physician will sign the form. The physician will review your medical history and medication use with you. Depending on the study, other additional examinations may also take place, such as a physical examination, measuring weight, blood pressure, temperature, heart monitoring, blood and urine tests, a pregnancy test, alcohol and/or drug tests, or other tests.

2. **Follow-up visits**:
   During the entire study, additional examinations may be scheduled, such as additional blood

tests or a visit for a specialized examination. These tests and/or examinations are always done by appointment. Retesting (verification of an abnormal result found during screening) is conducted within approximately 7 days after screening, by appointment.

3. **Overnight stay:**
   4 periods of 4 days and 3 nights each (leaving the unit and receiving visitors during the stay is not permitted).

4. **Ambulatory visit(s):** none

5. **Last visit - follow-up visit (first/second):**
   You will have a final examination to check your health status one last time. This is the end of your study participation.

Admission requirements

You may be eligible for a screening visit if you meet the conditions listed below.

General requirements:

Sex	**Male or female**
Age	**Between 18 - 60 years (inclusive)**
BMI	**Between 18.0 - 30.0 kg/m2** (calculate your BMI on cpu.be)
Body Weight	**Not less than 50kg**

Informed consent form (ICF)	Willing to sign the consent form and follow the restrictions.
Smoking	No use of nicotine-containing substances (e.g., cigar, nicotine patch, or e-cigarette) for 6 months before the screening and no smoking until the end of the study. Avoid smoky environments, BBQs, and charcoal fires.
Covid-19 infection	You did not have COVID-19 until 4 weeks prior to the first intake of the study medication (excluding being symptom-free AND having a negative COVID test 2 weeks after the start of symptoms or exposure). You have a negative COVID test upon entering the unit (Day -1 of each period for Part 1). You can also participate in the study if you are not vaccinated, but it is recommended to be vaccinated.
Alcohol and drugs	No alcohol or drug intake 24 hours before the intake of the study medication; until leaving the unit. There is no history of alcohol or drug abuse, either past or present.
Medication history	No use of prescription or over-the-counter medications (including vitamins, herbal supplements, etc.) 14 days before the study medication until the end of the study. Allowed: paracetamol, contraception, hormone replacement therapy.
Medical history	Generally healthy; you do not have any of the following diseases: Congenital anomalies. Gastrointestinal diseases: IBD, gastroparesis, celiac disease, toxic megacolon, dysplasia, gastroesophageal reflux disease, colon cancer, bowel strictures, or fistulas.

	Cardiovascular diseases, including cardiac arrhythmias and lipid disorders. Lung diseases. Gastrointestinal disorders. Kidney diseases, bladder-urinary tract diseases. Metabolic diseases: e.g., diabetes, thyroid problems. Infectious diseases: e.g., hepatitis B or C, HIV, tuberculosis. Blood diseases, including immune system disorders. Neurological disorders. Skin diseases. Musculoskeletal diseases: muscles/bones. Psychiatric illnesses. Cancer: skin, breast, lung, uterus. Other relevant diseases.
No surgery	3 months before the screening and up to 12 weeks after the last administration of the study medication.
Gastric reduction	Volunteers with a gastric reduction (e.g., gastric bypass, gastric band, etc.) are not allowed.
No blood donations/loss	From 3 months before the first administration of the study medication until after the study (more than 450 ml).
No egg (ova, oocytes) donation	During the study, up to 90 days after the last intake of the study medication.
No sperm donation	During the study, up to 90 days after the last intake of the study medication.
No allergies	Immune system reactions to foreign substances (such as certain medications or foods).
No participation in other studies	From 30 days before screening; up to 5 times the half-life of the study medication taken from a previous study. (Note: the longest period applies.)
Smooth blood collection	Blood draws must proceed smoothly from both arms.
Meals during stay	Standard meals are served in the unit. Participants must be willing to consume these. Non-vegetarian meals may contain (pork) meat. Breakfast on each dosing day must be fully consumed. Alternatives can be provided for vegetarians.
Food restrictions	- No food products containing poppy seeds from 72 hours before screening and 72 hours before entering the unit until the end of the last visit of each study period. -No products containing methylxanthines (e.g., chocolate, coffee, tea, or cola) 24 hours before screening/administration of the medication. -No alcohol 24 hours before entering the unit. -No excessive use of caffeine (i.e., no more than approximately 500 mg/day, as in 5 cups of tea or coffee or 8 cans of cola) for outpatient visits during the entire study (including the screening period).
No strenuous physical exercise	Jogging, weightlifting, or any activity that you are not accustomed to and that causes muscle fatigue is not allowed from 48 hours before entering the unit, during the stay in the unit, and from 48 hours before any visit to the CPU (including follow-up visits).

No staff member	No staff member or family member of personnel employed by Janssen Pharmaceutica, Johnson & Johnson, or CPU.

Conditions regarding contraception and reproduction:

- **Women – must meet:**

Either: Postmenopausal	More than 1 year without menstruation. Additional blood tests may provide further clarity regarding your menopausal status.
Either: sterilized	After removal of ovaries and/or uterus, tying or blocking the fallopian tubes. Please bring proof of the procedure to the screening.
Either: effective contraceptive method	During the study and for at least 90 days after the last dose of the study medication: • Oral, intravaginal, transdermal hormonal contraception • Contraceptive injection • IUDs • Hormonal IUD • Contraceptive implants • Sterilized partner • Sexual abstinence
Not be pregnant and/or become pregnant	Before, during, and up to 90 days after the study.
No breastfeeding	Before, during, and up to 90 days after the study.

- **Men – must meet all the following conditions:**

Condom	You must use a condom during the study and for at least 90 days after the last dose of the study medication.
Contraception	The female partner must use an acceptable form of contraception, such as the pill, an IUD, surgical sterilization, etc.
Not father a child	During the study and up to 90 days after the last study medication.

<u>Selection process for participation in the study</u>

The principal investigator decides based on your screening results whether you are eligible for the study. After the screening, you will be contacted by phone to inform you about the results.

You do not meet the study criteria?

- The (principal) investigator will call you with the reason why you cannot participate in the study.

Do you meet the study criteria?

- A random draw using an automatic computer system determines whether you are invited as an effective, reserve, or standby participant.

Have you been selected as an effective participant?

- You will arrive as scheduled.
- On the day of admission, it will be assessed whether you still meet the study criteria. If it turns out that you no longer meet the study criteria, you will not be able to participate in the study and will go home.

Have you been selected as a reserve participant?

- You will arrive as scheduled.
- On the day of admission, it will be assessed whether you still meet the study criteria. If it turns out that you no longer meet the study criteria, you will not be able to participate in the study and will go home.
- If an effective volunteer drops out, there is a chance that you may step in. Please note that you must be available for the entire schedule of the study.
- If you remain a reserve participant, you may leave the unit after the first dose.

Have you been selected as a standby participant?

- You will arrive on the day of arrival.
- If a volunteer drops out, there is a chance that you may step in. Please note that you must be available for the entire schedule of the study. If you do step in, it will be assessed whether you still meet the study criteria. If it turns out that you no longer meet the study criteria, you will not be able to participate in the study and will go home.
- If you do not step in as an effective or reserve volunteer, you may leave the unit after a maximum of 2 hours.

Study compensation

You will receive a compensation for your invested time and commitment.

- € 55 for the screening
- € 4310 (including screening compensation) for the full study
- € 295 (including screening compensation) for the reserve
- € 150 (including screening compensation) for the standby

For each visit, including additional visits for supplementary tests, you will receive a mileage reimbursement set at €0.4246 per kilometer. For a one-way trip, we reimburse a minimum of 24 kilometers up to a maximum of 100 kilometers.

No reimbursement will be paid if you test positive for drugs or alcohol during the screening.

If you terminate the study early, the principal investigator will determine the reimbursement based on the hours you have invested. You will receive a pro rata reimbursement, calculated according to the study protocol.

Payments for standby participants, reserves, and those not selected after screening will begin after the first dosing day of the study group. Payments for effective participants will start after the final follow-up. We maintain a payment period of approximately 6 to 8 weeks. Please notify the recruitment department of any changes to your bank account number in a timely manner to ensure smooth payment.

Both the study calendar and the reimbursement may change, depending on the protocol and/or decisions made by the Ethics Committee.

How to register?

Please register online preferably via:

- Our website: www.cpu.be
- Email: cpu@its.jnj.com

If you register, please provide us with the following information:

- First and last name
- Phone number
- SID – personal volunteer number (if known)
- Study number (= CPU525)
- The group you wish to participate in

During office hours (08:00 – 17:00), you can also register by phone at 0800 97 886 or +32(0)3 640 32 30.

Your response to this recruitment letter only indicates your interest in obtaining information and does not guarantee actual participation in the study.

Like CPU on Facebook: Clinical.Pharmacology.Unit
Follow us on Instagram: @Janssenklinischonderzoek