B7981086-1001	**A Study to Learn How Different Manufactured Products of the Study Medicine Called Ritlecitinib are Taken up Into the Blood in Healthy Adults When Taken on an Empty Stomach or When Taken With a Meal in Healthy Adults**

Pfizer Clinical Research Unit Brussels

Protocol Title:	A Phase 1, Open-Label Study in Healthy Participants to Investigate the Pharmacokinetics of Ritlecitinib Following Single Oral Administration of Modified Release Formulations Under Fed and Fasted Conditions
Protocol version	Protocol Amendment 1
EU-CT number:	2023-505603-23-00
Study medicine or study drug:	PF-06651600 (Ritlecitinib)
Sponsor of the study:	Pfizer Inc.
Study site:	Pfizer Clinical Research Unit (PCRU) Route de Lennik 808, 1070 Brussels, Belgium
Investigator (study doctor):	Constantino Kantaridis
Emergency contact:	0800 30 019 or +32(0) 2 556 70 03

Table of Content

I. Information vital to your decision to take part to the study

Introduction

You are being invited to take part in a clinical study (further on referred to as "study") to evaluate PF-06651600 (also referred to as "ritlecitinib", "study drug" or "study medicine"). A study drug is a medicinal product that is being tested or that is used otherwise (e.g., placebo, reference) for the needs of a clinical study.

PF-06651600 (ritlecitinib) is an inhibitor of an enzyme called Janus kinase 3 (JAK3). It reduces the activity of the enzyme "Jak 3" which plays an important role in inflammation.

Treatment with ritlecitinib is therefore expected to reduce the inflammatory responses in disease such as ulcerative colitis, Crohn's disease, alopecia areata, rheumatoid arthritis, and vitiligo.

You will not personally derive any benefit from your participation in this study, but the results obtained could be very important for the development of medicines and treatments which may benefit other people in the future.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation and possible risks, to allow you to take a decision with full awareness of all the implications. This is called giving an "informed consent".

Please read the following pages of information carefully and ask the investigator or his/her representative any questions you want. There are three parts to this document:

- the information vital to your decision to take part to the study;
- additional information;
- your written informed consent.

If you take part in this study, you should be aware that:

- This study is being conducted after having been reviewed and approved by an independent Belgian Ethics Committee and competent health authorities of Belgium (Federal Agency for Medicines and Health Products, "FAMHP").
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. However, even after having signed this document, you can stop participating in the study at any time, by informing the investigator of your decision.
- Further information about your "Participant Rights" can be found on page 17.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this study. Further information can be found in section "Insurance" on page 18.
- The information about your health and/or medical condition ("Personal Data") collected and processed in the scope of the study are confidential. This includes your medical history, some of your background information (for example your age, sex, and ethnic origin) and the results of examinations required by the study. Further information can be found in section "Protection of your Personal Data" page 18.
- You may contact the investigator or the Pfizer Clinical Research Unit ("PCRU") at any time, should you need any additional information.
- If you have separately expressed a specific consent for this, your general practitioner will be informed of your participation in this study. He/she will also be informed when the study is complete.

Objectives and description of the study protocol

The study involving PF-06651600 (ritlecitinib) will include an estimated amount of 12 participants. This study will take place at the Pfizer Clinical Research Unit (further referred to as "PCRU") in Belgium.

1. Purpose of the study

The purpose of this study is to evaluate the absorption of ritlecitinib by your body and to compare the amount of ritlecitinib in your blood after you take different formulations of ritlecitinib.

We will compare 2 new formulations of the ritlecitinib (modified release= MR) with the current formulation (Immediate release form (IR)). These 2 new formulations show different speed of release in the body (modified release "MR 1 and MR2") compared to the immediate release form (=IR).

Ritlecitinib will be administered for the first time as single dose of modified release formulations (MR1 and MR2).

This study will help to identify the most appropriate formulation with a maximized efficacy in the gastrointestinal indication.

2. Legal status of the study medicine

Ritlecitinib is a new study drug. The study drug is currently not approved for sale nor available in Belgium.

The study drug will not be made available to you by the PCRU after the study has ended. Because researchers are still studying this study drug, you can only have the study drug during your participation in the study, and not after you have finished taking part.

Course of the study

The study is planned to last for approximately 11 weeks.

Several examinations or procedures will be required in connection with the study:

- A screening examination.
- Period 1 to Period 4: 4 treatment periods, each period comprised of 3 days and 2 nights in the PCRU. The treatment periods will take place consecutively, with a total duration of 13 days and 12 nights in the PCRU (from Period 1 Day -1 (= admission) to Period 4 Day 3).
- The follow-up phone call will take place approximately 28-35 days after the last administration of the study drug.

1. COVID-19 risk assessments

Before being allowed to enter the premises of the PCRU, you may be asked to answer a questionnaire, undergo a temperature check and a sampling via the nose or the throat to screen for COVID-19. During the study period, you may undergo temperature checks and an additional test for COVID-19, if required. You may also be requested to wear a surgical mask as a safety measure to protect you from getting infected with COVID-19. PCRU is monitoring the evolution of the pandemic, measures may be updated (added or removed) based on the pandemic needs at a specific moment in time.

2. Screening examination

Before being allowed to take part in the study, you will undergo a medical examination, specifically an Electro Cardiogram (ECG) as well as a blood pressure, oral temperature, and heart rate measurements. Blood and urine samples (**for which you must have been fasting for at least 4 hours**) will be taken for laboratory tests and to screen for recreational and other drugs. You will nevertheless be allowed to drink water.

In addition, at screening:

- a hormone test will be carried out for post-menopausal women.
- a pregnancy test will be carried out for women of childbearing potential.
- a tuberculosis test will be done.

You will also be asked about your participation in clinical studies in the **30 days** preceding this screening examination.

For hygiene reasons, you are requested to take a shower before coming to the PCRU. In addition, to make it easier for the ECG electrodes to adhere to the skin, you are asked not to apply any moisturizing cream on your body prior to this visit.

3. Study period

If you agree to take part in the study and meet all the conditions required to be enrolled in the study, you will undergo the tests and examinations described below:

- Physical examination: at admission of Period 1 and on Day 3 of each period.
- Detection of recreational drugs in urine: at admission of Period 1.
- Single ECG: 5 measurement(s).
- Measurement of supine blood pressure and heart rate, and temperature: 5 measurement(s).
- Blood and urine samples for (safety) laboratory tests for which you will have to be fasting for at least 4 hours: 3 samples each for each Period and at the admission of Period 1.
- Pharmacokinetics (PK) blood samples to detect concentrations of study drug: up to 12 samples per period.
- Blood pregnancy test (only for women with childbearing potential): at admission of Period 1.
- Administration of the study drug (see section “Treatments administered during the study” on page 6).
- Faeces sample collection: Only when receiving Treatment C and E (MR2) up to 72 hours.

Each participant will have a follow-up phone call approximately 28-35 days after the last dose of study drug is taken.

The investigator may ask you to come in for additional tests, procedures, and assessments, if necessary, to protect your health (for more information, see section ‘**Special instructions for participants during the study**’ on page 13).

The remainder of your laboratory test samples and of the samples used to determine the study drug levels may be used for evaluation of i) exploratory safety biomarkers (see Glossary on page 27), ii) bioanalytical method (see Glossary on page 27), iii) as well as for other internal exploratory purposes related to this study drug. The remainder of your laboratory test samples may be retained for storage up to 1 year following completion of the study. These samples shall be destroyed after this timeframe or earlier if not used.

4. Treatments administered during the study

The planned treatments are:

Treatment A: ritlecitinib 100 mg oral solution
Treatment B: ritlecitinib 100 mg (2 × 50 mg) MR1 capsules in fasted state
Treatment C: ritlecitinib 100 mg (2 × 50 mg) MR2 capsules in fasted state
Treatment D: ritlecitinib 100 mg (2 × 50 mg) MR1 capsules FED
Treatment E: ritlecitinib 100 mg (2 × 50 mg) MR2 capsules FED

Sequence	Period 1, fasted**	Period 2, fasted**	Period 3, fasted**	Period 4, fed*
1	Treatment A	Treatment B	Treatment C	Treatment D
2	Treatment B	Treatment C	Treatment A	Treatment D
3	Treatment C	Treatment A	Treatment B	Treatment D
4	Treatment A	Treatment B	Treatment C	Treatment E
5	Treatment B	Treatment C	Treatment A	Treatment E
6	Treatment C	Treatment A	Treatment B	Treatment E

Each participant will receive each treatment once, 1 treatment per period. Depending on the treatment sequence that you will be assigned to, per the table here above.

The ritlecitinib treatment sequences will be assigned to you in a random manner as determined by computer, which is also called “randomization”.

(*) Fed condition, meaning:

- After an overnight fast (no eating) of at least 10 hours, you will be asked to eat a high-fat breakfast in its entirety within approximately 20 minutes, before taking the study drug.
- You are allowed to drink water until study drug administration.
- You will be allowed again to drink water one hour after you are given the study drug.

(**) Fasted condition, meaning:

- You will be asked to take the study drug after an overnight fast (no eating) of at least 10 hours.
- You will not be allowed to drink water for one hour before and one hour after you are given the study drug.

5. Specific Features of the study

5.1. High-fat breakfast

You may be given a high-fat breakfast before administration of study drug.

This high-fat breakfast will include eggs, minced beef or similar, whole milk, fried potatoes, and bread and butter.

You will be served breakfast 30 minutes before administrating the study drug. You must eat everything that you are given. You will have to finish the breakfast approximately 10 minutes before administrating the study drug.

5.2. Faeces collection (only for treatment C)

From Day 1 to Day 3 in Treatment C only, all bowel movements will be collected and transferred into a container (= 72-hour faeces collection). During your stay you will receive a high-fibre diet (e.g., dark bread, fruits like apples, apricots, prunes) and you will be asked to regularly drink water. In case you are not able to have a bowel movement every day, you may be asked to take a fibre supplement or laxative.

Possible Risks and Discomforts

1. Possible side effects

Ritlecitinib has been studied in healthy volunteers (in single doses up to 800 mg and multiple doses up to 400 mg daily for 14 days), participants with rheumatoid arthritis (at the dose of 200 mg daily for 8 weeks and 100 mg daily, alone or in combination with other medications, for 24 weeks), participants with alopecia areata (50 mg or 30 mg daily [with or without a starting dose of 200 mg daily for 4 weeks] for a total of 48 weeks, and for 3 years in some participants), and participants with vitiligo (50 mg daily [with or without a starting dose of 200 mg or 100 mg daily for 4 weeks] or 30 mg daily for a total of 48 weeks). Participants with ulcerative colitis were also studied (a starting dose of 20 mg, 70 mg or 200 mg daily for 8 weeks, followed by 50 mg daily for 24 weeks). There are also ongoing studies of ritlecitinib in participants with alopecia areata and Crohn's disease (at the dose of 200 mg daily for 8 weeks followed by 50 mg daily for a further 56 weeks). In completed and ongoing studies in alopecia areata and vitiligo, over 1600 participants have received ritlecitinib, which was generally safe and well tolerated.
In participants with alopecia areata receiving 50 mg ritlecitinib daily, the negative effects thought to be related to ritlecitinib and reported in more than 2% (1 in 50) of the participants were diarrhea (9.2%), acne (6.2%), urticaria (hives) (4.6%), rash (3.8%), and dizziness (2.3%).

1.1. Reactivation of viruses

Certain viruses can remain in the body and they may reactivate (wake up) and cause negative effects. In studies with ritlecitinib or other similar medications, reactivation of the chicken pox virus (varicella zoster virus) has caused shingles (herpes zoster), a skin condition with blisters, accompanied by burning or pain which may last after the rash clears), and reactivation of the herpes simplex virus has caused cold sores or fever blisters in the mouth or genital ulcers. It is not known if ritlecitinib could lead to the reactivation of hepatitis viruses. During the study, call your study doctor right away if you think you may have shingles, ulcers in the genital area, or cold sores.

1.2. Serious or Unusual Infections

Ritlecitinib works by affecting your immune system. Ritlecitinib can make you more likely to get infections or make worse any infection that you may already have. It can lower the ability of your body to fight infections, leading to serious infections or infections that usually don't occur in people with a normal immune system. A serious infection (which can be caused by bacteria, fungi, or viruses) means that you may have to stay in the hospital for treatment of the infection and/or receive treatment through an injection. A serious infection may potentially be life-threatening. You may need to temporarily (until the infection has cleared) or permanently stop your study treatment. Some people have had serious or unusual infections while taking ritlecitinib or other similar medications. You will not be allowed to participate in the study if you have any kind of infection at this time or if you have had any of the following infections in the past: please refer to the section 'Specific Exclusion criteria in this study' on page 13. After starting ritlecitinib, call your study doctor right away if you have any symptoms of an infection. Symptoms of an infection could include fever, weight loss or excessive tiredness or other symptoms specific to the site of infection, such as a persistent cough. You will be discontinued from the study if you develop a serious infection.

1.3. Cancer

Ritlecitinib or other similar medications may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphomas (a type of blood cancer) and other cancers, including skin cancers, have been reported in patients taking medications that work in a similar way to ritlecitinib. Cases of cancer (for example breast cancer and skin cancer) have been reported in clinical studies with ritlecitinib. Most people with a history of cancer will not be eligible for this study, except for those who have had successfully treated skin cancers that were not of the melanoma type and those who have had successfully treated local cancer of the cervix (the lower part of the uterus). Talk to your study doctor if you have had any type of cancer.

1.4. Changes in certain laboratory test results

Your study doctor will perform blood tests before you start taking ritlecitinib and while you take ritlecitinib. Some changes in blood tests that have occurred with ritlecitinib are described below. You will have these blood tests at study visits, and you will be discontinued from the study if certain blood tests change to a level which would cause concern for your continued participation in the study.

- Decreases in lymphocyte counts. Lymphocytes are white blood cells that help the body fight off infections. If your lymphocytes are low, you might be more likely to get an infection.
- Decreases in platelet counts. Platelets are blood cells that help blood to clot. If your platelets are low, you might be more likely to bruise or bleed. Although bleeding or bruising related to low platelets has not been seen in previous studies with ritlecitinib, there is still a potential risk that this could happen.
- Increase in levels of creatine phosphokinase, a protein derived from muscle. Creatine phosphokinase levels may increase after strenuous exercise or with damage to muscles.

1.5. Skin Effects

Events of rash, acne and urticaria (hives) occurred more often in those treated with ritlecitinib. Rash and urticaria (hives) could indicate an allergic reaction. The majority of events were reported as mild or moderate in severity. During the study, you should inform your study doctor if you notice any changes on your skin. In some cases, your doctor may take a skin biopsy (a small sample of skin that is cut and removed) to investigate a rash.
Photographs of a rash may also be taken.

1.6. Blood Clots

Medications that work in similar ways to ritlecitinib (JAK inhibitors) may increase the risk of developing a blood clot in your legs (deep vein thrombosis) or lungs (pulmonary embolism).
Cases of blood clots (including blood clots in the lungs) have been reported in clinical studies with ritlecitinib. You should seek medical attention right away if you have any symptoms that could be due to a blood clot in your legs (such as pain in your leg, swelling in the leg, a feeling of warmth in the leg, red or darkened skin on the leg) or due to a blood clot in your lungs (symptoms may include sudden shortness of breath, pain in your chest, coughing up blood, light-headedness, irregular heartbeat, excessive sweating, clammy or bluish skin). Tell your study doctor as soon as possible if you are diagnosed with a blood clot in your body.

1.7. Other Effects

Studies have been conducted in animals to identify risks that may occur in people that are given ritlecitinib. In studies with dogs, changes in the nervous system related to ritlecitinib were seen after 9 months of taking doses estimated to be 7.4 times above the 50 mg clinical dose. After 7 months, at even higher doses (estimated to be 33 times above the 50 mg clinical dose), a few dogs had hearing loss. All the changes in the nervous system and hearing loss got better after stopping the drug. Because the dog findings (single species) occurred only at doses higher than those to be used long-term in this study, it is unlikely that there are related human risks from ritlecitinib at the doses used in this study. However, hearing will be tested regularly in this study. If you develop symptoms that might be due to nervous system disease, you may be referred for additional evaluation by a doctor who specializes in diseases of the nervous system.
Adverse cardiovascular safety events (i.e., events involving the heart and blood vessels, including heart attacks and stroke) have been reported with medications that work in similar ways to ritlecitinib (JAK inhibitors). Inform your study doctor if you have had any type of heart or brain disease, such as a heart attack or a stroke. You should seek medical attention right away if you have any symptoms that could be due to a heart attack (such as pain or discomfort [lasting for more than a few minutes or that goes away and comes back] in your chest, jaw, neck, back, arms or shoulders, shortness of breath, cold sweat, clammy skin) or stroke (such as sudden numbness or weakness in one part or on one side of your body, sudden trouble speaking, sudden trouble seeing in one or both eyes, sudden loss of balance).
Tell your study doctor as soon as possible if you are diagnosed with a heart attack or stroke.

There may be rare and unknown side effects with taking ritlecitinib. Some of these side effects may be life threatening.
It is important that you report all side effects that you experience as soon as they occur, regardless of whether or not you believe they are caused by the study drug.
If you do not understand the risks described above, please ask the study doctor or study staff to explain them to you.

1.8. Pregnancy Related Risks/Use of Birth Control

In pregnant animals, ritlecitinib was associated with fetal changes in bones and some internal organs, and lower fetal body weights. Because of this and the investigational nature of ritlecitinib, it should not be administered to pregnant women or to women who are able to become pregnant who are unwilling or unable to use the required contraception for this study.
When ritlecitinib was administered to healthy women at the 200 mg daily dose (but not at the 50 mg daily dose) together with an oral contraceptive containing the hormone ethinyl estradiol, the level of ethinyl estradiol in the blood was decreased; the clinical significance of this decrease is unknown, however the efficacy of estrogen-containing contraceptives may be decreased. If you are able to become pregnant, the study doctor will discuss with you any acceptable contraception methods required to participate in this study.
When male rats were treated with ritlecitinib and mated with female rats that were not treated, there were smaller litter sizes due to fewer fertilized eggs attaching to the wall of the uterus in those female rats. There were no effects on sperm or other features of male reproduction. It is not known if the ability of men to father children is reduced while they are taking ritlecitinib.
Men in the study are not required to use birth control, because ritlecitinib is not likely to transfer to a partner through semen at blood levels that could harm the fetus.
It is not known whether ritlecitinib is secreted into human milk. Because of this and the investigational nature of ritlecitinib, it should not be administered to breastfeeding women.
Other currently unknown risks and discomforts could appear. It is therefore very important that any new health problem is quickly reported to the investigator, regardless of whether or not you think it has to do with the study.
As with any study, unexpected side effects may occur. If any significant findings or side effects were to come to light during this study, you would be notified.
In this case, you will be asked to sign either an addendum to the consent form or a new informed consent form.

Other currently unknown risks and discomforts could appear. It is therefore very important that any new health problem is quickly reported to the investigator, regardless of whether or not you think it has to do with the study.

As with any study, unexpected side effects may occur. If any significant findings or side effects were to come to light during this study, you would be notified.

In this case, you will be asked to sign either an addendum to the consent form or a new informed consent form.

2. Risks associated with the evaluation procedures specific to the study

2.1. Blood draws

Blood draws may cause fainting, dizziness, swelling of the vein (blood vessel), pain, bruising, or bleeding at the site of puncture. More specifically, the collections with Tasso OnePlus device may result into small skin incisions of about 5 mm that normally heal in few days. To avoid the repetitive incision at the same site, and to decrease the risk of abnormal scar forming process, you will be requested to choose a different collection site at each subsequent time point. There is also a slight chance of infection.

The total quantity of blood taken during the study will be approximately 150 mL.

The times for taking blood may change. Additional blood samples may be added provided the total volume of 550 mL is not exceeded during any period of 60 consecutive days.

Your body will quickly build up again this quantity of blood during the study.

2.2. ECG

The risks from an ECG can include skin irritation and a rash from wearing or removing the patches or shaving. If anything abnormal on ECG is seen, it may be necessary for you to have continuous ECG monitoring for some time for your own safety. This might mean that you are not able to move around very easily.

2.3. Fasting

Fasting could cause symptoms: of dizziness, headache, stomach discomfort, and/or fainting, it could also possibly cause hypoglycaemia (low blood sugar).

3. Contraception, pregnancy, and breast-feeding

3.1. For women:

Women of non-childbearing potential:

You may participate in this study, provided that:

- you are 18 years or older, **and**
- you are post-menopausal (meaning that your last period was at least one year ago, **or**:
  - you have been surgically sterilised (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy), **or**;
  - you have an ovarian failure.

If you do not fall into one of the abovementioned categories, you will be considered as capable of having children.

Women of childbearing potential:

If you are considered as being capable of having children and you take part in this study, you must use contraception (an effective birth control method).

At each visit to the PCRU, the investigator or PCRU staff will check you are using the appropriate method(s) of contraception.

If you wish to discontinue your contraception during the study, you must inform the investigator or PCRU staff without delay. You will be withdrawn from the study if you discontinue your contraception.

The study drug could bring about an unknown risk for an embryo, foetus, or breastfed baby during the study. During screening, at admission, at the end of each study period, you must have a pregnancy test with a negative result.

You must fulfil at least one of the conditions below:

- you have had a bilateral tubal occlusion;
- you have a non-hormonal IUD (intra-uterine device);
- you have a hormonal IUS (intra-uterine system);
- you use hormonal contraceptives, such as oral, intravaginal, injectable or transdermal, in combination with a barrier method (female or male condom).

- you use hormonal contraceptives such as implantable, in this case you do not require an additional barrier method.
- your partner has undergone a vasectomy at least six months ago;
- you are abstinent from heterosexual intercourse as your preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent.

These contraception methods must be used until at least 28 days after the last dose of study drug is taken.

3.2. For men:

No contraception methods are required for male participants in this study, given that research has shown that the study drug does not transfer through semen.

3.3. Pregnancy follow-up

You are not allowed to partake in this study if you are actively trying to conceive.

Any pregnancy during the study, either from a female participant or from the female partner of a male participant, or within at least 28 days after the last administration of study drug, should be immediately reported to the investigator or his/her team. The investigator will ask if you/your partner or your health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. If you/your partner agree, this information will be provided to the sponsor for safety follow-up.

II Additional information

Restrictions

1. Common restrictions

You should avoid all **prescription and non-prescription medications, or supplements** (including vitamins, extracts of plants, homeopathic medicines, and medicinal herbal teas) from:

- 7 days prior to first dosing, throughout the duration of the study and up to the day of final payment;
- You will have to declare to the PCRU staff all treatments taken during 28 days before first dosing.

If you fall ill and require treatment, please contact the investigator or PCRU staff immediately. You will be told what treatment you may undergo or whether it is preferable to discontinue the study.

You must also avoid consuming **any alcoholic drinks or caffeine-containing products (such as coffee, tea, or other beverages) and products containing poppy seeds**, from:

- 24 hours before screening, prior to the start of dosing and during the confinement.

You must also avoid any **strenuous physical exercise**, from:

- 48 hours before the screening, and prior to each blood collection.

You must also avoid consuming **tobacco-or nicotine**-containing products from:

- 24 hours prior to dosing, during confinement and throughout each study period.

Furthermore, you may not consume **red wine, grapefruits or grapefruit juice or citrus fruit of the grapefruit type (pomelos, « Seville » oranges or bitter oranges)** from:

- 7 days prior to the first period and during conferment in the PCRU.

2. Specific restrictions to this study

There aren't any further restrictions to this study.

Exclusions

1. Common exclusions

You may not take part in this study if:

- You are under f the lower limit of this study for age (18 years or older) or weight (minimum of 45 kg), or outside the limits for Body Mass Index (16-32 kg/m^2).
- You are regularly taking prescription and non-prescription medications or supplements, or you are suffering from a chronic illness.
- You have taken or you are taking recreational drugs.
- You have an illness, or any condition that may affect absorption of the medicines (for example a partial or full surgical removal of the stomach).
- You are suffering from asthma or from any allergy to a medicine.
- You are suffering from any symptomatic, seasonal allergies (hay fever) and require treatment.
- You smoke more than 5 cigarettes a day or consume an equivalent quantity of tobacco / nicotine-containing products.
- You have taken part in another clinical study involving investigational medicines within the last 30 days.

- You have given blood or constituent elements of blood (platelets) during the two months preceding participation in the study, or you intend to be a donor in the two months following the end of the study (Red Cross standard to guarantee blood cells regeneration). Giving plasma is allowed.
- You think you are at risk of being infected with the AIDS virus, hepatitis B or C.
- You have a history of regular alcohol consumption exceeding 14 drinks/week (1 drink = 90 mL of wine or 240 mL of beer or 30 mL of spirit).

2. <u>Specific exclusions criteria in this study</u>

You may not take part in this study if:

- You have received a vaccine with live attenuated virus within 6 weeks prior to the first dose administered.
- You have any of the following acute or chronic infections or infection history:
  - Any infection requiring treatment within 2 weeks prior to the first dose administered.
  - Any infection requiring hospitalization, parenteral antimicrobial therapy within 60 days of the first dose of study drug.
  - Any infection judged to be an opportunistic infection or clinically significant by the investigator, within the past 6 months of the first dose of study drug.
  - Known active or history of recurrent bacterial, viral, fungal, mycobacterial or other infections.
  - History of recurrent (more than one episode of) localized dermatomal herpes zoster, or history of disseminated (single episode) herpes simplex or disseminated herpes zoster.
- You have history of febrile illness within 5 days prior to the first dose of study drug
- You have history of any lymphoproliferative disorder such as Epstein Barr Virus (EBV) related lymphoproliferative disorder, history of lymphoma, history of leukemia, or signs or symptoms suggestive of current lymphatic or lymphoid disease.
- You have presence or a history of malignancy other than a successfully treated or excised non-metastatic basal cell or squamous cell cancer of the skin or cervical carcinoma in situ.
- You have a history or active latent or inadequately treated tuberculosis infection.

Special instructions for participants during the study

You must:

- be willing and able to follow all scheduled visits, instructions and other study procedures;
- not take part in any other clinical studies involving an investigational treatment, be it a medicinal product, a medical device and/or a procedure, while taking part in this study;
- always carry the “emergency card” with you and show this card to any health care provider if you seek emergency care during this study. This card includes information about the study that will help the health care provider treat you. This is imperative for your safety in the event of emergency care. It also mentions a telephone number that you may call in an emergency. You should return this card to the PCRU staff at the end of the study;
- come to the PCRU within 24 hours if the investigator asks you to come back for a visit to check on your well-being. You are asked to not make any travel plans that will prevent you from adhering to this condition;

- inform the investigator or PCRU staff of:
    - Any information relating to your state of health, or the symptoms you are experiencing;
    - Any prescription and non-prescription medications or supplements that you have taken or received in the last 28 days, that you are currently taking or that you intend to take;
    - Any change in treatment that has taken place during the study;
    - Any study exclusion criteria that would apply to you according to the information given by the investigator or PCRU staff;
    - Any significant illness, past or present, including any consultation you have had with any doctor during the last six months, whether or not it resulted in medication or a medicine prescription;
    - Your history of recreational and other drug taking, alcohol consumption or smoking tobacco;
    - Your participation in other clinical studies during the last 30 days.

Benefits

This study is for research purposes only. There will be no direct benefit to you from taking part, but information learned from the study could be very important for the development of medicinal products and treatments may help other people in the future.

Incidental findings

During the study new information about your health might be discovered by chance. This is called “incidental findings”. Such information may be important to you or your blood relatives’ health.

The investigator may discuss the results with you if the incidental findings are related to you. If you prefer not to be informed of any of these incidental findings, please indicate this by checking the box at the signature page.

Process for participants who wish to end study participation

Your participation in a clinical study is voluntary and must remain free of any coercion. This means that you have the right not to take part in the study or to withdraw at any time without giving a reason, even if you previously agreed to take part. Nevertheless, it may be useful for the investigator and the sponsor of the study to know if you are withdrawing from the study due to any constraints or discomforts.

Tell the investigator if you decide to stop so that you can end participation in the safest way.

You may be asked if this decision to withdraw is just to stop receiving the study drug or also to stop taking part in study procedures and/or post treatment study follow-up. If you agree to continue with the follow-up part of the study, information about your health will continue to be collected as described above in the procedures.

If you disagree to continue with the follow-up part of the study, you must inform the investigator in writing (by sending a simple email, for example).

The sponsor will use information and biological samples already collected from you in the study before your withdrawal. You may request that any samples that have been collected from you as part of the study be destroyed. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to you, or the samples may have been used up.

It is also possible that the investigator withdraws you from the study because he/she thinks it is better for your health or because he/she finds out that you are not following the instructions given to participants or for of another reason that will be explained to you.

Finally, the competent national or international authorities, the ethics committee that initially approved the study or the sponsor may decide to interrupt or discontinue the study because the information gathered shows that the study drug causes more side effects or more serious side effects than anticipated, or for any other reason, such as, for example, the decision to stop research and development of the study drug.

You should be aware that the decision to end study participation may have an impact on the study compensation as can be found on page 24.

Compensation for your study participation

Your compensation for the time loss due to your participation in the study will be available three weeks after the last contact (see point 11 of the "Participant Agreement and Consent Form" on page 24).

The compensation amount for this study is **€ 2802.00** (two thousand eight hundred and two euros).

You will receive the compensation amount in full if you participate to the study for its entire duration.

If you decide to withdraw your consent for **your** study participation, you will receive a compensation proportional to the duration of your participation **to the study.**

In case the investigator decides to withdraw you from the study, **because you become pregnant during the study, because you are not respecting the study restrictions or for another reason that will be explained to you,** you will receive a compensation proportional to the duration of your participation **to the study.**

However, if you would need to end your study participation for medical reasons evaluated by the investigator as related to the study participation**,** you will receive a full compensation of the amount mentioned in point 11 of the "Participant Agreement and Consent Form" on page 24.

If your study participation is ended because of a decision from the authorities, Ethics Committee, or the sponsor**,** you will receive a compensation proportional to the duration of your participation **to the study**.

If you would enter the study at a later stage than the beginning of the study, you shall receive a compensation proportional to the duration of your participation **to the study at this later stage.**

If changes are made to the original calendar of the study as provided at the time of first dosing, the compensation amount will be reviewed proportionally to the duration of the new calendar **of the study.**

In addition, you will be compensated for your travel expenses (a lump sum) based on the journey from the address **where you** officially reside, and the number of journeys made.

You will be paid using Clincard (Greenphire®), this is a sort of debit card. The PCRU staff will inform you about the practical arrangements.

Contact

In case of questions, you can contact:

Name/Function	**In case of**	**Contact details**
The PCRU	Information, problems, concerns	0800 99 256/ +32(0) 2/556 70 02, or 00800 2636 2636 for calls from the UK, France, Germany, and the Netherlands Email: PfizerVolRecruitment@pfizer.com
Emergency contact	Emergency	0800 30 019/ +32(0) 2 556 70 03
Insurance Company of the sponsor: **Chubb European Group SE**	disagreement or complaint on a damage claim	+32 (2) 516 97 11 *Policy number*: BECANA07085
Participants Recruitment Department	To exercise your rights of consultation, correction, or deletion of your data; and for any question related to the confidentiality of your data.	please send a signed and dated letter to the following address: Participants Recruitment Department Pfizer Clinical Research Unit Route de Lennik 808 1070 Brussels Or send an email to: PfizerVolRecruitment@pfizer.com, or werespectyourprivacy@pfizer.com
Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	Data Protection Authority Rue de la Presse 35, 1000 Brussels Tel.: +32 (0)2 274 48 00 Fax: +32 (0)2 274 48 35 Email: contact@apd-gba.be https://www.dataprotectionauthority.be/contact-us

Information on protecting participants and their rights

Study Review and Results

The documents of the study have been reviewed by

- The Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and
- An independent Belgian Ethics Committee

It is the task of the competent health authorities and the Ethics Committees to protect people who take part in a study. The health authorities will ensure that the study is conducted in accordance with the applicable legislation.

You should not under any circumstances take their approval as an incentive to take part in the study.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by legislation. This website will not contain information that can identify you. It will be no more than a summary of the general results of the study. The ClinicalTrials.gov website is in English only. The study results, when available, also be found on www.pfizer.com.

A summary of the results of the study, and a summary presented in terms understandable to a layperson, will be made available in the EU clinical trial database (https://euclinicaltrials.eu/), no matter what the study's outcome. To the extent possible, these summaries will be made available in the EU clinical trial database when the summaries become available. This website will not include information that can identify you. The EU clinical trial number is 2023-505603-23-00.

If you would like any help in understanding the content of the abovementioned websites, please ask the investigator or PCRU staff.

Participant rights

If you agree to take part in the study, you must sign this informed consent document. The investigator or his/her representative will also sign this form and will thereby confirm that she/he has provided you with all the necessary information on the study. You shall receive a paper or an electronic locked copy of this document.

Before signing, do not hesitate to ask any questions that come to mind and to discuss your participation with a trusted person (for example friends, relatives, general practitioner, …) if needed.

Your participation in this study is voluntary and you must remain free from any constraint. This means that you have the right not to take part to the study or to withdraw from it, at any time, without giving any justification and without losing your legal rights, even if you previously agreed to take part to it.

You will be informed of any new scientific data that may influence your decision to take part or not in the study.

If you decide to withdraw from the study, you should inform the investigator and undergo some follow-up visits so that investigator or PCRU staff can be sure that you are in good health.

The investigator can decide to remove you from the study, if she/he deems that it would be harmful for you to continue to take part to it.

The study may also be discontinued further to the discovery of new information concerning the study drug or in the event that the Ethics Committee takes a new decision on the study.

Insurance

Any clinical study carries a risk, however small it is. Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the study. The sponsor has taken an appropriate insurance (a so called "No Fault insurance") for this liability. A copy of the insurance certificate can be obtained from the investigator or PCRU staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the study, you must inform your investigator or PCRU staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the study is possible, he/she will inform the sponsor. The sponsor will then immediately initiate the declaration procedure to the insurance company. If the company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the study. The insurance does not cover the natural progression of your disease/condition or the known side effects of the treatment you would have received without taking part to the study (that is your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. For contact details, consult section “contact” on page 16 .

Protection of your Personal Data

Your Personal Data will be handled in compliance with the EU Regulation 2016/679 (the General Data Protection Regulation also referred to as “GDPR”) and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their Personal Data.

This section describes how we, the study site (PCRU) and the sponsor (Pfizer), will collect, use, transfer, store, analyse and share (called “processing”) your Personal Data, because we are conducting scientific research and based upon your consent**.**

1. **<u>What Personal Data may be collected about you during this study?</u>**

In order to conduct the study and comply with legal and regulatory requirements, the investigator and PCRU staff will collect information about you. Information about you may include:

- **Information that directly identifies you,** such as your first name and surname, address, telephone number, e-mail address, date and place of birth, national ID number.
- **Your bank account number.**
- **With your consent, the identification of your general practitioner.**
- **Sensitive Personal Data** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive Personal Data if needed for this study such as ethnic origin, genetic information, sexual orientations, HIV/AIDS, tuberculosis, dietary preferences.
- **Data from this study, testing and analysis of biological samples** (such as blood or urine) **and images** (such as X-rays, CT-Scans, and medical photographs). This may also include genetic information.
- **Data captured from electronic devices,** if you complete the consent process using the eConsent tablet or if you use a mobile application or other digital tool during the study. This information may include data about your use of the eConsent tablet, application or tool, such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, your electronic signature. Mobile applications

and other digital tools used in the study may have their own privacy policies. Those policies provide additional information about the data processing activities performed by the digital tools.

If required by this study, the investigator and PCRU staff may also collect biological samples from you and take images of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history, you should inform that person or those persons you have done so and that their information will be used as described in this document and applicable law.

2. How will your Personal Data be used and how long will they be used?

The study site (PCRU) is the data controller of the Personal Data maintained at the study site. Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The study site will retain your Personal Data for the period necessary to fulfil the purposes outlined in this section and/or for the maximum period permitted by applicable law, which could **be up to 25 years** after the end of the study.

Your Personal Data may be accessed and used by:

- The investigator and the PCRU staff;
- The sponsor (including its affiliated companies) and its representatives, for example, auditors;
- People and/or organizations providing services to, or collaborating with, the sponsor;
- Any organization that has or obtains rights to the study drug or that obtains all or part of the sponsor's business;
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study
- Government or regulatory authorities (including those in other countries, such as the United States Food and Drug administration or the European Medicines Agency).

Under certain circumstances, information that identifies you by name may leave the study site in connection with the study and be sent to a vendor contracted by the sponsor, in order to support the use of digital tools (e.g., electronic consent, mobile applications) in the study.

The people and/or organizations contracted by the sponsor to provide these services must keep your personal information private, and they will not share with the sponsor any information that can directly identify you.

Typically, your first name and name will be removed from your information before it is sent outside the study site. Your first name and surname will be replaced with a unique code before your information (and/or your biological samples and/or images, if collected as part of the study) leaves the study site. This information is referred to as your “Coded Information”. The study site will keep the link between the code and your name confidential. The sponsor (Pfizer) is the controller of your Coded Information. The sponsor’s employees and those with whom your Coded Information is shared are required to protect your Coded Information and will not attempt to re-identify you. Data generated using biological samples and images of you, if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this section. Sometimes the study site may be unable to remove information that can identify you from your images (for example if images must be taken from areas of your face, or if images would contain identifiable marks such as tattoos, birth marks or scars), meaning that the images shared with others may be identifiable as yours.

The individuals and groups listed above will use your Personal Data, including your Coded Information, to:

- conduct this study;
- comply with legal or regulatory requirements, including for all of the purposes listed in this consent document and to seek approval from government or regulatory agencies to market the study drug;
- determine if you are eligible for this study;
- provide you with reimbursement for your time, effort and certain expenses related to your participation;
- verify that the study is conducted correctly, and that study data are accurate;
- answer questions from IRB(s), IEC(s), or government or regulatory agencies;
- publish the study results;
- contact you during and after the study (if necessary);
- protect your vital interests or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- improve the quality, safety, and design of this study and other research studies.

The sponsor may also be required to provide information gathered from this study, including your Coded Information, to regulatory authorities for public disclosure. In such cases, the sponsor will take steps to minimize the risk that you could be re-identified.

Some of the people and/or organizations using your Personal Data may be based in countries other than your country of residence, including the United States. When transferred to countries with legal standards that have not been found by the European Commission to offer an adequate level of protection of Personal Data, the sponsor uses officially approved EU agreements (called “Standard Contractual Clauses”) to ensure a similar degree of protection is afforded. A copy of these Standard Contractual Clauses may be obtained by contacting your study team.

The sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in this consent document, indefinitely or for the maximum period permitted by applicable law after the end of the study.

3. Can your Coded Information, biological samples and/or images if collected as part of the study, be used for other research?

Yes. The sponsor may use your Coded Information, biological samples and/or images, if collected as part of the study, in the future, to support and advance other scientific research projects, including research supporting public health aims.

At this time, the specific details of these research projects are not known; however, your Coded Information could be used in combination with data from other sources, not related to you or this study, in connection with other research and development activities (and the associated scientific publications), which may concern:

- The way ritlecitinib and drug of the same group work,
- The diseases/conditions for which ritlecitinib is evaluated in this study, or
- Other diseases and health problem which could benefit from ritlecitinib, or from related diagnostic tests.

This Coded Information, biological samples and/or images, if collected as part of the study, could also be used for research about the investigational medicinal product(s).

Reasonable safeguards will be used to protect your Coded Information, biological samples and/or images used in any other research and will include: (a) limiting access to individuals bound by duties of

confidentiality; (b) taking steps to minimize the risk that you could be re-identified; and (c) obtaining approval of Ethical Review Boards/Committees.

However, if your Coded Information, biological samples and images (if collected as part of the study) are anonymized such that they can no longer be identified with you, they may be used for other research purposes, without any additional safeguards.

4. What are your rights to your Personal Data?

You are entitled to ask the study site what Personal Data are being collected about you and how those data will be used in connection with the study.

- You have the right to inspect, and request access your Personal Data that is held about you by the study team. To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.
- You have the right to correct or update your Personal Data.
- You have the right to limit the collection and use of your Personal Data under certain circumstances (for example, if the information is inaccurate).
- You have the right to receive your Personal Data in a structured, commonly used and machine-readable format (for example, in a readable text electronic file or chart) for your own purposes or for giving it to others. *You do not have the right to receive your Personal Data that have been used for public interest purposes (for example, for reporting incidents of disease to public health officials) or in the exercise of official authority vested in the sponsor or the PCRU (for example, responding to information requests from public agencies or monitoring drug safety).*
- You have the right to request the deletion of your Personal Data if you are no longer participating in the study and you have withdrawn your consent to process your Personal Data as described in this document. *However, there are limits to the ability to honour a request to delete your Personal Data. Some or all of your Personal Data may be kept and used if deletion would seriously impair the study (for example, if deletion would affect the consistency of study results) or if your Personal Data is needed to comply with legal requirements.*

To exercise your rights of consultation, correction or deletion, please write to the address listed in section “Contact” on page 16.

Should communicating your Personal Data potentially jeopardise the results of the study, we may ask you to wait until the end of the study to access these Personal Data.

Your Personal Data will be deleted by the sponsor and will no longer be stored or processed by us (except for your letter requesting the removal). You will therefore not be able to participate in any of our future studies.

However, if you have taken part in a study or a screening examination, the sponsor will not be able to delete all your Personal Data, but your file will be inactivated, and you will not be contacted again.

You also have the right to file a complaint with the Data Protection Authority of the place where you live, work or where any breach of data protection law may have occurred.

5. What happens to your Personal Data, biological samples and images, that may be collected as part of the study if you do not wish to continue with the study?

As noted in this consent document, you are free to stop taking part in this study at any time by informing the study team of it.

If you stop taking part in the study and you do not inform the study team about your withdrawal, your contact information may be used by the study team to contact you or your general practitioner, or to search publicly available records to find out how you are doing. These uses of your Personal Data may continue until the sponsor determines the study is complete, which may take many years or until you withdraw your consent, as described below. If you stop taking part in the study, but do not withdraw your consent to

processing your information, your Personal Data will continue to be used in accordance with this consent document and applicable law, as the sponsor needs to manage your Personal Data in specific ways in order for the research to be reliable and accurate.

The sponsor may continue to use your Coded Information even if you stop taking part in some or all of the study activities as necessary for the sponsor (a) to comply with its legal and regulatory obligations; (b) for the sponsor's legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of its products and advancing public health and scientific research and publishing the results of its studies; and (c) any other purposes permitted under applicable data protection and privacy laws.

No new Personal Data, biological samples and images will be collected about you or from you by the study team, unless you have told the study team that you agree to provide new Personal Data or samples. Even if you do not agree to the collection of new Personal Data or samples, the study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to the sponsor.

In the event the sponsor has already removed all information that could reasonably be used to identify you, it may use all resulting anonymized data for any purpose even if you stop taking part in the study or withdraw your consent to the processing of your information.

Any biological samples that have been collected from you will be handled as described in the "Process for Participants who Wish to end study participation" section in this consent document (page14).

Monitoring of non-participation in other clinical studies

The PCRU takes part in the "Verified Clinical Trials LLC" ("VCT") programme.

The aim of this database is to enable us to ensure that participants are not taking part in several clinical studies at the same time. In addition, this system will enable us to enhance your protection, as well as the quality of the data for the study that you will be taking part in.

For more information regarding VCT, please refer to the separate VCT consent form.

(page left blank intentionally)

III PARTICIPANT AGREEMENT AND CONSENT FORM	
Investigator	**Constantino Kantaridis**

1. I freely agree to take part in this study.
2. I have received full explanations from the investigator or PCRU staff in charge of the study about the nature, purpose, and likely duration of the study, and about what is expected of me. I have also been informed of all the possible side effects. This information is an integral part of this document. I have informed the investigator of my medical history, of the medications I may have taken, and of any other studies I may have participated in.
3. I have been given the opportunity to question the investigator on all aspects of the study and have understood the advice and information given as a result. I have been given sufficient time to consider my decision to participate.
4. I have been informed that a blood sample will be taken for HIV, Hepatitis B and C screening and tuberculosis tests.
5. As mentioned on page 14 it is possible that incidental findings would come to light during this study that could be of importance to your health or the health of your relatives.

   OPTIONAL CONSENT, WITH NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS STUDY

   Please indicate if you want to be informed of incidental findings that are related to you **(Tick as appropriate. If you leave this question open, we assume the answer is 'Yes, I want to be informed'.)**

☐ **No, I do not want to be informed**	☐ **Yes, I want to be informed**

6. I agree to comply with any instruction given during the study and to co-operate faithfully with the investigator and to tell him/her immediately if I suffer any change of any kind in my health or well-being or any symptoms of whatever kind.
7. I undertake to be present on the premises of the Pfizer Clinical Research Unit (PCRU) for the whole period spent in hospital, and also for the outpatient visits scheduled within the context of this study. I am aware of the fact that non-compliance with this obligation could be detrimental to my health if I experienced an undesirable effect and could not immediately gain access to the appropriate medical care.
8. I shall not donate blood during the study, nor for two months before or after the study.
9. I undertake to comply with the study restrictions as they are mentioned under "II. Additional information" (page 12). If a violation of these commitments were confirmed by laboratory tests, I could be excluded from the study.
10. It is understood that I am free to leave the study at any time without having to justify my decision and without losing my legal rights. However, I shall, in that case, continue to benefit from all treatments and check-ups my condition may require.
11. The sponsor confirms that:

    i) I shall receive the sum of **€ 2802.00** (two thousand eight hundred and two euros) for my participation to the study for its entire duration.

    If I need to withdraw from the study for medical reasons evaluated by the investigator as related to the study participation, I shall however receive a full payment of the above-mentioned amount for my participation.

If I decide to withdraw from the study or if I need to withdraw from the study because I become pregnant during the study, I am not respecting the study restrictions, for another reason that was explained to me or because the study is ended by decision of the authorities, I shall receive a compensation proportional to the duration of my participation.

If I enter the study at a later stage than the beginning of the study, I shall receive a compensation proportional to the duration of my participation to the study at this later stage.

If changes are made to the original calendar of the study as provided at the time of first dosing, the compensation amount will be reviewed proportionally to the duration of the new calendar of the study.

In addition, **I will be compensated for my travel expenses** (a lump sum) based on the journey from the address where I officially reside, and the number of journeys made.

ii) A provision has been made for no-fault insurance to cover research injury liability of the sponsor established in relation to the study.

12. The study site (PCRU) and the sponsor each request your consent to collect, use, transfer, store, analyse and share the Personal Data referred to in this consent document for the purposes of: (1) responding to the questions of the study and guaranteeing its integrity; (2) ensuring high standards of quality and safety of its products to advance public health and scientific research in the public interest; (3) publishing the results of studies; and (4) improving the quality, design and safety of this study and other research studies, including developing diagnostic products and tools. You don't have to provide your consent. Please however note that if you are not willing to provide your consent to the processing of your Personal Data, you will not take part to this study. If you agree to such processing of your Personal Data for these purposes in accordance with the terms of this consent document, please sign this form.

    The study site and the sponsor may also process your Personal Data without your consent in accordance with applicable law or legal and/or regulatory obligations.

    If you have any questions or wish to withdraw your consent to the processing of your Personal Data, please contact the PCRU and not the sponsor. Withdrawal of consent before the completion of the study activities may require you to stop taking part in some or all of the study activities. Such withdrawal will not affect the lawfulness of any processing up to that point.

13. By signing this consent document, I consent to the processing of my Personal Data, including my Coded Information, as set out in this consent document. I also consent to these Personal Data being transferred to and processed in countries other than Belgium.

Signatures:

In agreement, the participant:

_____

First and last name of participant (in capital letters)

_____ _____

Signature of participant Date of signature§

§Participant must personally date their signature.

Person Obtaining Consent:

I hereby confirm having provided the participant with all the necessary information about the study, without exercising any pressure to cause the participant to take part in the study. I have ensured that the participant has understood the information on the study. I further confirm that I am willing to answer any additional questions if necessary. I state that I operate in compliance with the ethical principles set out in the "Helsinki Declaration" and the European and Belgian legislation in application.

_____

First and last name of the Person Conducting the Consent Discussion (in capital letters)

_____ _____

Signature of the Person Conducting the Consent Discussion † Date of Signature

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

Glossary

Alopecia areata: A condition in which hair is lost from some or all areas of the body, also known as spot baldness.

Bilateral oophorectomy: Ablation (surgical removal) of the ovaries.

Bilateral salpingectomy: Surgical removal of the fallopian tubes.

Bioanalytical method: Techniques used to measure the quantity of study drug, metabolite, biomarkers or proteins.

Biomarker: A biomarker is a characteristic objectively measured and evaluated as an indicator of a disease or of the action of a medicine. Thus, for example, glucose is a biomarker for diabetes, and blood pressure is a biomarker for arterial hypertension (high blood pressure).

Body Mass Index: The Body Mass Index is calculated by dividing your weight (in kg) by your height (in m) squared. In practice, you just need to divide your weight by your height and then once again divide the result by your height. For example, if you are 1.70 m tall and you weigh 70 kg, your BMI index will be 24. This is calculated as follows: 70 kg / 1.70 m = 41 and 41 / 1.70 m = 24.

Crohn's disease: A type of inflammatory bowel disease that may affect any part of the gastrointestinal tract from the mouth to the anus.

Enzyme: Protein produced by the body which enables the activation or acceleration of chemical reactions.

Exploratory safety biomarkers: Biomarkers that are being researched and not yet validated. The objective of these biomarkers is to develop (and validate) a (new) safety indicator which can be used as safety endpoint in future clinical trials.

Gastrectomy: the medical procedure where all or part of the stomach is surgically removed.

Glycaemia: Concentration of sugar in the blood.

Hysterectomy: Ablation (surgical removal) of the uterus.

Hypoglycaemia: low blood sugar level.

Immediate release: A formulation that allows an immediate delivery of the study drug after its administration.

Modified release: A formulation that allows progressive delivery of the study drug after its administration.

Metabolite: Compound resulting from the transformation of a medicine in a cell, in a tissue or in blood.

PCRU: Pfizer Clinical Research Unit, located at Route de Lennik 808, 1070 Brussels, Belgium. Also referred to as "study site".

Pharmacokinetics (PK): Assessment of the evolution of study drug concentrations in the blood before and after administration.

Plasma: The liquid portion of the blood that bathes the other blood components (red blood cells, white blood cells, platelets).

Protein: Biological molecule composed of amino acids brought to the body through food processing by digestion followed by assimilation by the intestines, among others.

Rheumatoid arthritis: A chronic inflammatory disorder causing joint swelling, most commonly from the wrist and the hands.

Ulcerative colitis: A bowel disease that causes long-lasting inflammation and ulcers (sores) of the colon (large intestine) and rectum.

Vitiligo: A skin condition characterized by patches of the skin losing their pigment.