| | |
|---|---|
| **C4531001-1002** | **A PHASE I, RANDOMIZED, DOUBLE-BLIND, SPONSOR OPEN, PLACEBO-CONTROLLED, DOSE ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE AND MULTIPLE INTRAVENOUS AND SUBCUTANEOUS DOSES OF PF-07275315 IN HEALTHY PARTICIPANTS** |

| | |
|---|---|
| EudraCT number: | 2022-000854-27 |
| Study medicine: | PF-07275315 |
| Sponsor of the study: | Pfizer Inc. |
| Research organisation: | Pfizer Clinical Research Unit (PCRU), Route de Lennik 808, 1070 Brussels |
| Medical Ethics Committee: | Comité d'Ethique Hospitalo-Facultaire Erasme-ULB. |
| Principal Investigator (study doctor): | Alexandre Stouffs |
| Emergency contact: | 0800 30 019/ +32(0) 2 556 70 03 |

# Contents

| | |
|---|---|
| **C4531001-1002** | **A PHASE I, RANDOMIZED, DOUBLE-BLIND, SPONSOR OPEN, PLACEBO-CONTROLLED, DOSE ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE AND MULTIPLE INTRAVENOUS AND SUBCUTANEOUS DOSES OF PF-07275315 IN HEALTHY PARTICIPANTS** |

Pfizer Clinical Research Unit Brussels

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

**Introduction**

You are being invited to take part in a clinical study to evaluate an investigational medicinal product. An investigational medicinal product is a medicinal product that is still being studied to evaluate its efficacy, safety or mode of action.

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 will benefit other people.

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 these few pages of information carefully and ask the investigator or his/her representative any questions you want. There are 3 parts to this document:

- the information essential to your decision,
- your written informed consent and
- supplementary information (appendices) detailing certain aspects of the basic information.

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

- This clinical study is being conducted after having been reviewed and approved by one Ethics Committee and the federal agency for medicines and health products.
- 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 that document, you can stop participating in the study at any time, by informing the investigator of your decision.
- The data collected in the scope of the study are confidential and shall be processed in conformity with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data. Your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time, should you need any additional information.
- If you have 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.

Further information about the "Participant Rights" can be found in appendix (page 19).

## Objectives and description of the study protocol

We are inviting you to take part in a clinical study involving PF-07275315 (referred to as the "study drug") which will include around 77 participants at approximately 4 research sites in the United States and Belgium.

The research study may use competitive enrolment. This means that when a certain number of people have entered the research study from all research sites combined, no one else will be allowed to participate. It is possible that you may not be allowed to join the research study.

The study drug is an investigational drug being studied to treat people with atopic dermatitis (AD). AD is a form of eczema (itchy, inflamed skin rash). This will be the first time that the study drug will be given to humans.

### 1. AIMS OF THE STUDY

The purposes of this study are:

- To see how a new drug under study is tolerated, if there are significant side effects, and how people feel after receiving single or multiple doses
- To measure the amount of study drug in your blood after single or multiple doses
- To evaluate if your body develops antibodies (an immune response) after the administration (single and multiple doses) of the study drug in healthy adults.
- The pharmacodynamics of PF-07275315 will also be studied, this means that the effect of study drug on certain blood biomarkers (cytokines) involved in the immune response is evaluated.

### 2. LEGAL STATUS OF THE STUDY MEDICINES

PF-07275315 is a new investigational medicine. A new investigational medicine is one that is currently not approved for sale in Belgium.

### 3. POSSIBLE SIDE EFFECTS

PF-07275315 is a new type of antibody (a protein that the body uses to fight infection) that targets 3 proteins (known as cytokines) that are believed to be important in causing the inflammation seen in skin diseases such as atopic dermatitis (eczema) and related diseases. Inhibition of these cytokines alone have been shown to be safe and well tolerated in humans and to have benefit in treating atopic dermatitis and / or asthma. However, the safety and effectiveness of inhibiting all 3 cytokines at the same time have not been studied in people.

PF-07275315 has never been given to people before. Therefore, the safety, toleration, and potential side effects of PF-07275315 in humans are not known. Studies have been conducted in animals to try to identify risks that may occur in people given PF-07275315.

PF-07275315 has been tested in monkeys for months to see if it would likely be safe to give to people and to identify any possible undesirable side effects. No side effects were identified in this study even at the highest dose tested that produced levels of PF-07275315 in the blood over 10 times the maximum predicted blood levels planned in human clinical trials. Animal studies cannot entirely predict symptoms that may arise after administration of PF-07275315. There may be rare and unknown side effects, including reactions that may be life-threatening.

Based on a test in which blood cells were exposed to PF-07275315 in a test tube (that is, outside the body), PF-07275315 may have a low risk of causing release of certain proteins (known as cytokines) that could result in a condition known as cytokine release syndrome (CRS). CRS is a serious condition that could result in a need for hospitalization. CRS is easily monitored in the clinic. Other studies have shown that PF-07275315 has a low risk of binding to proteins (known as complement) that start a process normally used by the body to fight infections and destroy germs. If this process is started when there is no infection, there is a risk that the proteins will attack normal cells. To minimize the possible risks of CRS and complement binding, we are only giving PF-07275315 to people in a controlled clinical setting in early clinical studies. Dosing in the first clinical trial will start at a very low dose. Doses in this first study will be increased gradually and only if the lower dose is well-tolerated.

PF-07275315 can cause the body to form antibodies (proteins in the blood that identify and help destroy invaders, like bacteria) to the drug. Any foreign protein (including any other antibody drug) can cause these antibodies to form – this is not specific to PF-07275315. These antibodies could affect the potential for you to be treated successfully with PF-07275315 or similar drugs in the future. It may also increase your likelihood of becoming allergic to this or similar drugs in the future. PF-07275315 may also cause reactions at the site of injection.
At this time, it is not known whether PF-07275315 can cause fetal harm when administered to pregnant women. Animal reproductive studies have not been conducted with PF-07275315. It is also not known whether PF-07275315 can affect the ability of males or females to have children, or whether PF-07275315 is secreted in human milk. For this reason, pregnant and women nursing an infant cannot take part in early clinical studies with PF-07275315, and women who are able to have children will need to use appropriate contraception (birth control) to prevent pregnancy and will be monitored for pregnancy periodically during early clinical trials.
PF-07275315 has not been tested in animals to see if it can cause or increase the risk for cancer. However, antibody drugs like PF-07275315 generally have a low risk for causing cancer.
All drugs that reduce inflammation may increase the risk of infection. The cytokines targeted by PF-07275315 are involved in fighting infections with parasites, like worms (helminths). Other drugs that work like PF-07275315 generally have a low risk of infection. However, until more human data are available, participants in early clinical trials should try to avoid travel to areas where parasites like worms (helminths) are common.
All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue, or neck. Other allergic reactions may include rash, hives, or blisters.

Other currently unknown risks and discomforts could appear. It is therefore very important that any new health problem is quickly reported to the doctor, regardless of whether or not you think it has to do with the study.
Because the study drug is investigational, all of its side effects are not known. There may be rare and unknown side effects. These include reactions that may cause sickness or death.

All drugs have a potential risk of an allergic reaction. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help (by calling 112 or immediately going to an emergency room) and contact the study doctor right away if you think you have any of the following symptoms:

- Trouble breathing;
- Wheezing;
- Difficulty swallowing;
- Swelling of the face, mouth, lips, gums, tongue, or neck.

Other allergic reactions may include:

- Itchiness;
- Rash;
- Hives;
- Blisters;
- Palpitations (racing heart);
- Chest discomfort/tightness;
- Muscle pains/stiffness.

At times, the following may also be symptoms of an allergic reaction:

- Diarrhea;
- Nausea;
- Vomiting;
- Abdominal pain.

Participants who experience a significant side effect during the study may have the following additional procedures done:

- Tests or treatment(s) may be given as needed for your safety.
- A catheter may be inserted into a vein in your arm so that you may be given IV fluids and/or medications.
- Depending on the severity of your symptoms are, you may be referred to outside medical providers or a hospital for additional evaluation and/or treatment.
- The study investigator may notify your emergency contact as appropriate in the event of an emergency while you are taking part in the study.

As with any study medicines research, unexpected side effects may occur. If any significant findings or side effects were to come to light during the course of 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.
The study medicines will not be available after the study has ended.

**Course of the study**

Part A (Single dose IV (intravenous) infusion)

If you are in Cohort (group) 1 or 2, you will be in this study for up to about 299 days.
Several examinations or procedures will be required in connection with the study:

- A screening examination
- 1 dosing period of 5* overnight stays at the Pfizer Clinical Research Unit (PCRU). You will not be able to leave the PCRU during that time.
  (*admission may be on Day -2 or Day -1)
- 8 planned follow-up visits

If you are in Cohort 3 through 8, or Cohort 12 (optional, may not be done), you will be in this study for up to about 569 days.
Several examinations or procedures will be required in connection with the study:

- A screening examination
- 1 dosing period of 5* overnight stays at the PCRU. You will not be able to leave the PCRU during that time.
  (*admission may be on Day -2 or Day -1)
- 11 planned follow-up visits

Part B (Multiple dose SC (subcutaneous) injection)

If you are in Cohort 9, 10 or 11 (optional, may not be done), you will be in this study for up to about 589 days.
Several examinations or procedures well be required in connection with the study:

- A screening examination
- 3 dosing periods with separate admissions. Each dosing period has 5* overnight stays at the PCRU. You will not be able to leave the PCRU during that time. There will be at least 2 weeks between each dosing period.
  (*admission may be on Day -2 or Day -1)
- 12 planned follow-up visits

## 1. SCREENING EXAMINATION

Before being allowed to take part in the study, you will undergo a medical examination, specifically an ECG as well as a blood pressure, oral temperature, respiratory rate, heart rate, height and weight 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 drugs. You will nevertheless be allowed to drink water. A hormone test will be carried out for post-menopausal women and a pregnancy test will be carried out for women of childbearing potential.

You will also complete a questionnaire about your participation in clinical studies in the 365 days preceding this screening examination.

For hygiene reasons, you are requested to take a shower before this visit.
To make it easier for the ECG electrodes to adhere to the skin, we ask you not to apply a moisturizing cream on your body.

## 2. 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:

For Cohort 1-8 and 12 (if done)

- Physical examination:
  - During confinement: 2 examinations
  - During outpatient visits: 9 examinations
- Detection of drugs in urine: at admission for each period.
- Single 12-lead ECG:
  - During confinement: 6 measurements
  - During outpatient visits: 9 measurements
- Triplicate 12-lead ECG
  - At admission
- Measurement of supine blood pressure and oral temperature:
  - During confinement: 5 measurements
  - During outpatient visits: 10 measurements (including pulse rate)
- Measurement of respiratory rate
  - During confinement: 3 measurements
- Measurement of body weight
  - During outpatient visits: 2 measurements
- Continuous cardiac monitoring (see section “Specific features of the study” on page 16) on Day 1.
- Administration of the study medicine (see the section “Treatments administered during the study” page 9).
- Blood and urine samples for laboratory tests:
  - During confinement: 3 samples
  - During outpatient visits: 10 samples
- Blood samples to determine the concentrations of PF-07275315:
  - During confinement: 9 samples
  - During outpatient visits: 11 samples
- Retained Research Samples for biomarkers:
  - During confinement: 32 samples
  - During outpatient visits: 53 samples
- Blood sample for immune response assessment:
  - During confinement: 1 sample
  - During outpatient visits: 10 samples

For Cohort 9-10 and 11 (if done)

- Physical examination:
  - During confinement: 6 examinations
  - During the outpatient visits: 8 examinations
- Detection of drugs in urine: at admission for each period (3 times)
- Triplicate ECG
  - During confinement: 5 measurements
- Single 12-lead ECG:
  - During confinement: 14 measurements
  - During outpatient visits: 11 measurements
- Measurement of supine blood pressure, pulse rate and oral temperature:
  - During confinement: 13 measurements
  - During outpatient visits: 12 measurements
- Measurement of respiratory rate:
  - During confinement: 3 measurements
- Administration of the study medicine (see the section “Treatments administered during the study” page 9).
- Blood and urine samples for laboratory tests:
  - During confinement: 6 samples
  - During outpatient visits: 15 samples
- Blood samples to determine the concentrations of PF-07275315:
  - During confinement: 10 samples
  - During outpatient visits: 12 samples
- Retained Research Samples for biomarkers:
  - During confinement: 1 sample
- Retained Research Samples for biomarkers:
  - During confinement: 48 samples
  - During outpatient visits: 39 samples
- Blood sample for immune response assessment:
  - During confinement: 3 samples
  - During outpatient visits: 9 samples

For safety reasons, we may add procedures at any time during the study in order to check on your health status.

After the last administration of the study medicine, you will return to the PCRU for a planned series of follow-up visits **for which you must have been fasting for at least 4 hours**.
The planned follow-ups are as follows:

- Days 8, 15, 32, 46, 61, 91, 181, and 271 - Cohorts 1 and 2
- Days 8, 15, 32, 46, 91, 181, 271, 361, 451, and 541 – Cohorts 3 – 8 and 12
- Days 36, 51 66, 81, 111, 201, 291, 381, 471, and 561 – Cohorts 9, 10 and 11

When participating to the study, you must be able to come to the PCRU within 24 hours if we need to call you in for a check-up. We therefore ask you not to make any travel plans that will prevent you from respecting this condition.

The remainder of your laboratory test samples and of the samples used to determine the study medicine and biomarkers levels 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. The samples may be used for evaluation of exploratory safety biomarkers, bioanalytical method, as well as for other internal exploratory purposes related to this study medicine.

## 3. TREATMENTS ADMINISTERED DURING THE STUDY

Study drug (PF-07275315) and placebo (contains no active study drug) will be given as an intravenous (IV) infusion, through a small tube placed in a vein in one of your arms, or as a subcutaneous (SC – under the skin) injection(s).

The planned treatments are:

Part A – Single dose IV

| COHORT # | # OF PARTICIPANTS | Treatments administered on Day 1 |
|---|---|---|
| 1 | 4 | 0.3 mg study drug or placebo |
| 2 | 4 | 1 mg study drug or placebo |
| 3 | 4 | 3 mg study drug or placebo |
| 4 | 6 | 10 mg study drug or placebo |
| 5 | 6 | 30 mg study drug or placebo |
| 6 | 8 | 100 mg study drug or placebo |
| 7 | 8 | 300 mg study drug or placebo |
| 8 | 8 | 1,000 mg study drug or placebo |
| 12* | 5 | TBD# mg study drug or placebo |

*Optional Cohort
#TBD – to be determined (based on information from the previous cohorts in Part A)
Doses in this part of the study may be adjusted depending on the study drug levels in the blood of participants in the previous cohort. Other doses may be explored in additional cohorts of participants.

Study drug (PF-07275315) and placebo will be given by IV injection or infusion in one of your arms, depending on the volume of study drug or placebo to be administered.

Part B – Multiple dose SC

| COHORT # | # OF PARTICIPANTS | Treatments administered on | | |
|---|---|---|---|---|
| | | Day 1 | Day 15 | Day 29 |
| 9 | 8 | 100 mg study drug or placebo | 100 mg study drug or placebo | 100 mg study drug or placebo |
| 10 | 8 | 300 mg study drug or placebo | 300 mg study drug or placebo | 300 mg study drug or placebo |
| 11* | 8 | TBD# mg study drug or placebo | TBD# mg study drug or placebo | TBD# mg study drug or placebo |

*Optional Cohort
#TBD – to be determined (dose strength, frequency, and route of administration (IV or SC) will be based on information from the previous cohorts in Parts A and B)

The planned doses for Cohort 9 may be adjusted depending on the information from Part A of the study.

The study drug and placebo will be given by SC injection(s) to your abdomen (belly)

The dose(s) that you will receive is/are compounded in our pharmacy for use in this study. Compounded means that the ingredients are added together and mixed to make the final dose.

Study drug or placebo will be given after breakfast in both Part A & B.

PF-07275315/placebo will be administered in a random distribution determined by computer, which is also called randomization. This means, it will be randomly assigned, like the flip of a coin, who receives either the study drug or placebo.

You have about a 1 in 2 chance of receiving placebo during the study if you are in Cohorts 1, 2 or 3.

You have about a 1 in 3 chance of receiving placebo if you are in Cohorts 4 or 5.

You have about a 1 in 4 chance of receiving placebo if you are in Cohorts 6, 7, 8, 9, 10, or 11 (if done).

You have about a 1 in 5 chance of receiving placebo if you are in Cohort 12 (if done).

Neither you nor the study staff will know whether you are receiving PF-07275315 or placebo during the period in progress, but the staff will be able to obtain the study medicine identity if necessary.

**Contraception, pregnancy and breast-feeding**

**1. FOR WOMEN ONLY:**

## Women of non-childbearing potential:

You may participate in this study provided that:

- You are between 18 and 65 and
- You are post-menopausal (meaning that your last period was at least one year ago).
- OR ELSE 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 these categories (described above), you will be considered as capable of having children.

## Women of childbearing potential:

The risks of the study medication on the female reproduction and for foetal harm have not yet been studied and are therefore still unknown. Therefore, at each visit to the PCRU, we will check that you are using the appropriate contraception.

You must fulfil one of the conditions below:

- You have had a bilateral tubal occlusion
- You have a non-hormonal IUD
- You have a hormonal IUS
- Your partner has undergone a vasectomy at least six months ago
- You use hormonal contraception
- 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.

In addition, an effective barrier method (e.g. condom) must be used when a combined or progesterone-only hormonal contraception method is used.

These contraception methods must be used until minimum 450 days after last administration of study medicine intake or until the end of the study.

Taking the medicine during the study could bring about an unknown risk for an embryo, foetus or breastfed baby. That is why you must have a negative pregnancy test during screening, at the start and end of each study period and at each follow-up visit when the test is performed.

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

**2. FOR MEN ONLY:**

Research has shown that the study medicine does not transfer through semen, therefore no contraception methods are required for male participants in this study.

**3. PREGNANCY FOLLOW UP**

Any pregnancy during the study, either from a female participant or from the female partner of a male participant, or 450 days (or longer for higher doses – could be adapted based on the emerging data as required during the study conduct) after the treatment with the study medicine stopped, should be reported to the study doctor or his/her representative immediately. The study doctor will ask if you/your partner or your pregnancy doctor is 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 study sponsor for safety monitoring follow-up.

**Risks associated with the evaluation procedures specific to the study**

**1. BLOOD DRAWS AND IV CATHETERS (IF USED)**

Possible side effects of having your blood drawn or an IV catheter inserted include:

- Bleeding at the site of the needle puncture;
- Bruising;
- Feeling faint;
- Rarely, infection or blood clot;
- Redness of the vein;
- Inflammation of the vein;
- Swelling;
- Pain;
- Nerve damage;
- Vein irritation from the fluid or medication being given;
- Local swelling due to IV fluid accidentally entering the tissue rather than the vein;
- Scarring.

If you feel faint, tell one of the study staff immediately.

**2. ECG AND CONTINUOUS HEART MONITORING (TELEMETRY)**

Possible side effects from having an ECG and continuous heart monitoring include:

- Irritation or rash from the adhesive on the patches

A rash may result in a long-lasting discoloration of your skin. If it is necessary to shave the area where the patches need to be, irritation from shaving may occur.

**3. COVID-19 TESTING**

Collection of a swab sample may cause:

- Discomfort
- Sneezing
- Your eyes to water
- Gagging
- Possible nosebleed

## 4. FASTING

Fasting could cause symptoms such as:

- Dizziness;
- Headache;
- Stomach discomfort;
- Fainting;
- Hypoglycaemia (low blood sugar).

## 5. TESTING OF DNA AND/OR RNA

Genes are pieces of DNA that, through material called RNA, give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. DNA, RNA, and proteins can be studied as part of genetic research. This study may involve studying your biology and whether a particular biological feature (including genes) is related to the effects or action of the study medicine or to a disease. This may include analysing all of your genetic information (called “whole genome sequencing”). Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes. The genetic analysis is for research purposes only and is not a medical test. This means that the medical importance of the results may not be known, or that they may not be related to any medical condition.

## Benefits

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 drugs and treatments which will benefit other people.

## Withdrawal from the study

Your participation is voluntary and you are entitled to withdraw from the study for any reason, without having to justify your decision. Nevertheless, it may be useful for the investigator and for the sponsor of the study to know if you are withdrawing from the study because the constraints or discomfort of the treatment are too great (too many uncomfortable side effects, for example).

You may be asked if this decision to withdraw is just to stop receiving the study medicine 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 study doctor in writing.

The sponsor will use information and samples already collected from you in the study before your withdrawal.

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.

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 investigational treatment 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 medicine.

## Samples of biological material collected during the study

The sponsor of the study undertakes that the samples will only be used as defined in this section.

### RETAINED RESEARCH SAMPLE

For Cohort 1-8 and 12 (if done)

| | Days on which samples are taken | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 5 | 15 | 32 | 61 | 91 | 181 | 271 | 361 | 451 | 541 |
| 4 mL | X | | | | | | | | | | | |
| 6 mL | X | X | X | X | X | X | X | X | X | X | X | X |
| 2.5 mL | X | X | X | X | X | | | X | | X | | X |
| 2x4 mL | X | | X | | X | | | | | | | |

For Cohort 9-10 and 11 (if done)

| | Days on which samples are taken | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 5 | 15 | 16 | 29 | 30 | 51 | 111 | 201 | 291 | 381 | 471 | 561 |
| 4 mL | X | | | | | | | | | | | | | |
| 6 mL | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| 2.5 mL | X | X | X | X | X | X | X | X | | X | | | | X |
| 2x4 mL | X | | X | X | | X | | X | | | | | | |

These sample will be used to study biological substances in your sample(s), including your genes. This will help us learn more about the study medicine.

These samples are called “Retained Research Samples”
The sample will be held by Pfizer for up to 50 years. Research results will not be communicated to you or your doctor.
Specimens will be stored in a Pfizer-designated facility, which is currently located at 2910 Fortune Circle West, Suite E, Indianapolis, Indiana, 46241 in the United States.

The sample taken of your biological material is considered to be a “donation” and you should know that, as a matter of principle, you will not receive any financial benefit (royalties) related to the development of new therapies derived from the use of your donation of biological material and that could have commercial value.

If you withdraw your consent for participation in the study, you may contact the investigating physician to have the unused portion of your sample destroyed. The results obtained based on your samples before the withdrawal of your consent will remain the property of the sponsor of the study.

## If you take part in this clinical study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal any information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- Not to take part in other clinical study involving an investigational treatment, be it a medicinal product, a medical device or a procedure, while taking part in this study.
- To carry the "emergency card" with you at all times. This is imperative for your safety in the event of emergency care in an institution that does not know you. This card states that you are taking part in a clinical study. It also mentions a telephone number that you may call in an emergency. You should return this card to us at the end of the study.

## Contact

If you need further information, but also if you have problems or concerns, you can contact the Pfizer Clinical Research Unit on the following telephone number +32(0) 2/556 70 02.

# II. Supplementary information

## Restrictions

### COMMON RESTRICTIONS TO MOST OF THE STUDIES

You should avoid all medications including non-prescription medicines bought, including vitamins, extracts of plants, homeopathic medicines and medicinal herbal teas, in the four weeks before the study, throughout the study and up to the day of final payment. If you fall ill and require treatment, please contact the PCRU immediately. You will be told what treatment you may undergo or whether it is possibly preferable to discontinue the study.

You must also avoid consuming any alcoholic drinks, stimulants (such as coffee, tea, chocolate or beverages containing caffeine or theine), bread or cakes containing poppy seeds:

- from 24 hours before the screening examination until the results of your tests are known,

***then***

- from 24 hours before the start and throughout each study period, **and lastly**
- from 24 hours before the follow-up visits.

You must also avoid any strenuous physical exercise:

- from 48 hours before the screening examination until the results of your tests are known,

***and***

- from 48 hours before the start and throughout each study period, **and lastly**
- from 48 hours before the follow-up visits.

You must also avoid consuming tobacco-or nicotine-containing products from 24 hours before the start and throughout each study period and also from 24 hours before each follow-up visit. You will not be allowed to smoke while confined in the PCRU during the study period.

## Exclusions

### 1. SPECIFIC EXCLUSIONS FROM THIS STUDY

You may not take part in this study if:

- You show signs of active or latent tuberculosis infection or a history of untreated or inadequately treated tuberculosis infection.
- You have an acute or chronic infection, or a history of (recurrent) infections.
- You have a recurrent history of Herpes simplex and/or Herpes Zoster.
- You fail to comply with vaccination schedule as recommended by the Belgian authorities.
- You have had recent exposure to live or attenuated vaccines within 28 days of the screening visit.
- You have undergone significant trauma or major surgery within 1 month of the first dose of study drug.

### 2. COMMON EXCLUSIONS TO MOST OF THE STUDIES

You may not take part in this study if:

- You are outside of the age limits (18-65 years) or weight limits (minimum of 50 kg), or you are outside of the limits of the Body Mass Index (17.5 - 32 kg/m$^2$).
- You are regularly taking medications or you are suffering from a chronic illness.
- You are suffering from asthma or from any allergy to a medicine.
- You are suffering from any treated or symptomatic, seasonal allergies (hay fever).
- 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 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 have taken or you are taking drugs.
- 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).

## *Supplementary information on the risks associated with participation in the study*

## Specific features of the study

### 1. BLOOD VOLUME

The total quantity of blood taken during the study will be approximately 770 mL for Part A and 970 mL for Part B.
The times for taking blood may change. Additional blood samples may be added, provided the total blood volume taken during the study does not exceed 550 mL during any period of 56 consecutive days.

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

### 2. INTRAVENOUS INFUSION

In this study PF-07275315 will be administrated intravenously through a catheter, which is a thin flexible tube that can be inserted into a blood vessel (vein), enabling blood samples to be taken or liquid to be injected. The catheter will be placed on Day 1 in a vein of your forearm and you could feel a little pain when the catheter is placed.

### 3. SUBCUTANEOUS INJECTION

In this study PF-07275315 will be administrated subcutaneously (under the skin) in several locations of your body, such as the arms, thigh or abdomen. During a subcutaneous injection, a needle is inserted under the skin, rather than into a vein. The injection sites will be determined by the study staff.

## 4. INJECTION SITE CHECK

In order to be able to evaluate the tolerability of the study medicine we will examine the site of injection using a specific non-invasive test using a scale (for example: pain, skin reaction, etc.…). This test will be performed several times during the study.

## 5. TELEMETRY

Telemetry consists of a painless recording of your heart activity. For this, you will wear a small case which will be linked to 10 electrodes (similar to ECG electrodes) placed on your chest. The apparatus itself is connected by a wireless link to a central computer that analyses your heart activity and enables us to monitor it in real time. Telemetry will generally be recorded for a minimum of 8 hours.
There will also be a recording for 2 hours, in the same conditions at the start of the study, that will be used as the starting point for comparisons with the telemetries taken after administration of the study medicine.

## Glossary

**Antibody:** a protective protein produced by the immune system to identify and neutralize substances which the body recognizes as non-body substances, such as bacteria and viruses.

**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 medicine, metabolite, biomarkers or proteins.

**Biobank:** Reserve of biological samples.

**Bioequivalence:** Comparison of different drug formulations based on analysis of concentrations in blood in function of time.

**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.

**Cytokines:** Small proteins involved in the immune response signalling.

**DNA:** A molecule that is present in all cells, and which comprises the entire set of information necessary to the development and working of an organism. It is also the support of the heredity, because it is wholly or partly transmitted in the course of reproduction. It therefore carries the genetic information (the genotype) and constitutes the genome of living beings.

**Hysterectomy:** Ablation (surgical removal) of the uterus.

**Immunogenicity profile:** The immunogenicity profile will measure if your body develops antibodies (an immune response) after dosing with the study drug

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

**Pharmacodynamics (PD):** The study of what the drug does to the body (mechanism, action).

**Pharmacokinetics (PK):** Assessment of the evolution of study medicine 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.

**RNA:** A biological molecule that is present in practically all living organisms, including certain viruses. The RNA is a molecule that is chemically very similar to DNA and it is also in general synthesised in the cells based on a DNA matrix of which it is a copy. Living cells use RNA in particular as an intermediary support for the genes to generate the proteins they need. The RNA can fulfil numerous other functions and in particular intervene in chemical reactions taking place in the cell.

**Additional information on protecting participants and their rights in each clinical study**

***You must inform the study doctor or his/her representative of:***

- Any medicine or substance that you have taken 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 doctor in charge;
- 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 drug taking, alcohol consumption or smoking tobacco;
- Your participation in other clinical studies during the last 12 months.

## *Assistance or advice*

This study has been submitted to an independent Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', which has issued a favourable ethical opinion as regards to its implementation. The Ethics Committees are responsible for the protection of the subjects who take part in clinical research in accordance with the Law of 7 May 2004 concerning experiments on humans.
However, the decision as to whether or not to participate in this study must be your own personal decision. Under no circumstances should you take the Ethics Committee's favourable opinion as an incentive to take part in this study.

If you have any questions, concerns or complaints concerning the role of the Ethics Committee or your rights as a participant in a clinical study, you may contact the Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', during office hours, dialling the following number: 02/555 37 07.

A description of this clinical 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. You can check this website at any time. However, it may take several years before the research results are available online.

The ClinicalTrials.gov website is in English only. If you would like any help in understanding the contents of this website, please talk to your study doctor or his/her representative.

## *Participant rights*

Before signing, do not hesitate to ask any questions that you consider useful. Take the time to discuss it with a person you trust if you so wish.

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 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.

If you decide to withdraw from the study, we ask you to inform the study doctor and to undergo some follow-up examinations so that we can be sure that you are in good health.
The doctor in charge of the study 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 product or in the event that the Ethics Committee takes a new decision on the study.

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

If you agree to take part in the study, you must sign the informed consent form. The study doctor, or designee, 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 copy of that document.

### *Compensation and insurance*

Your compensation for the inconveniences caused by your participation to the study will be available three weeks after the last contact (see point 12 of the "Participant Agreement and Consent Form").

Any clinical study carries a risk, however small it is. If you suffer damage as a result of your participation in this study, you (or in the event of death, your dependants) will be compensated for this damage by the study sponsor in accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004). You do not have to prove a fault for this. In this regard, the sponsor has taken out an insurance policy.

You are therefore asked to report any new health problem to the investigator before consulting another doctor, taking any other medication or receiving any other medical treatment. If, for any reason, you consult another doctor during this clinical study, you must inform him/her that you are taking part in a clinical study and present your clinical study participant card. This could be important in establishing a diagnosis and treating your complaints.

If the investigator believes that a link with the study is possible (the insurance does not cover the natural progression of your disease or the known side effects of your normal treatment), he/she will inform the study sponsor, which will initiate the declaration procedure to its insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your new health problems and the study.

In the event of disagreement either with the investigator or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependents may bring proceedings against the insurer directly in Belgium (Insurer: Chubb European Group SE, policy number: BECANA07085, Tel: +32 (2) 516 97 11).

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer's registered offices.

Provision has been made for insurance to cover research injury liability of the sponsor established in relation to the clinical trial.

### *Protection of your personal data*

Your participation in the study means that you accept that the study doctor will collect data related to you (the "Personal Data") such as your name, postal address, email address, phone number, your date and place of birth, sex, age, your general practitioner's name (with your consent), bank details, as well as ethnic origin and data relating to your health status, and that the study sponsor (Pfizer) will use this Personal Data for research purposes as specified in this document, and for scientific and medical publications on that research (fully anonymously).

Your Personal Data will be collected, stored, accessed and otherwise processed in compliance with the applicable EU and Belgian laws on clinical trial, and with the applicable EU and Belgian privacy legislations as they may be amended or repealed and replaced from time to time (collectively referred to as "Data Privacy Laws") and as specified in the annex "Supplement related to personal data protection" (p. 25).

You have the right to consult, correct or request deletion of your Personal data by writing to the following address: Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels. 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.

If you want to ask for removal of Your Personal Data, please send a signed and dated letter to Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels. Your data will be deleted by Pfizer and will no longer be stored or processed by us (except for your letter requesting the removal – see point G of the "Supplement related to personal data protection"). You will therefore not be able to participate in any of our future studies.

However, if you have taken part to a study or a screening, we will not be able to delete your data, but your file will be inactivated, and you will not be contacted again.

**Monitoring of non-participation in other clinical studies**

Our Pfizer Clinical Research Unit, located on route de Lennik 808, 1070 Anderlecht (Brussels) 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 phase I 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.

## PARTICIPANT AGREEMENT AND CONSENT FORM

| Principal Investigator | Dr Alexandre Stouffs |
|---|---|

1. I freely agree to take part in this study.
2. I have received full explanations from the 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. The information document, which was sent to me, is attached hereto and is an integral part thereof. I have informed the study doctor of my medical history, of the medications I may have taken, and of any other studies I may have participated in. In this regard, I was given the Study Information Leaflet pertaining to the abovementioned study.
3. I have been given the opportunity to question the study doctor on all aspects of the study and have understood the advice and information given as a result.
4. I have been informed that a blood sample will be taken for HIV, Hepatitis B and C screening. I have also been informed that a blood sample will be taken, to study biological substances including my genes, to help us learn more about the study drug. The sample will be held in a Pfizer-designated facility for up to 50 years.
   Research results will not be communicated to me or my doctor.
5. I agree to comply with any instruction given during the study and to co-operate faithfully with the study doctor 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.
6. I undertake to be present on the premises of the Pfizer Clinical Research Unit 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.
7. I shall not donate blood during the study, nor for two months before or after the trial.
8. I undertake to comply with the study restrictions as they are mentioned under “II. Supplementary information” (page 15). If a violation of these commitments were confirmed by laboratory tests, I could be excluded from the study.
9. I understand that data about me will be collected throughout my participation in this study and that the Investigator and the Sponsor of the study will guarantee the confidentiality of these data.

   I agree to my personal data being processed as described under “Protection of your personal data” in the section “Additional information on protecting participants […]” (page 19). I also consent to these data being transferred to and processed in countries other than Belgium.
10. Although my name must never appear in the report of the study disclosed to third parties, I expressly authorise the company Pfizer to pass on the results of this study to the competent medical or pharmaceutical authorities, both Belgian and foreign, to technical advisers, whether or not linked to the company, and to publish the results.
11. 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.

12. The company sponsoring the study confirms that:

i) I shall receive the sum of **€ 11 295.00** (eleven thousand two hundred ninety-five euros) for my participation in the whole Part A of the study (until Day 541).

I shall receive the sum in several instalments:

- After the PCRU confinement I shall receive €1 393,00 (one thousand three hundred and ninety-three euros)
- At each ambulatory visit, of which there are 11, I shall receive €250,00 (two hundred and fifty euros) for a total of €2 750,00 (two thousand seven hundred and fifty euros)
- At the end of the study (until Day 541) I shall receive €7 152,00 (seven thousand one hundred and fifty-two euros)

I shall receive the sum of **€ 12 963.00** (twelve thousand nine hundred sixty-three euros) for my participation in the whole Part B of the study (until Day 561).

I shall receive the sum in several instalments:

- After the PCRU confinement I shall receive €2 751,00 (two thousand seven hundred and fifty-one euros)
- At each ambulatory visit, of which there are 12, I shall receive €250,00 (two hundred and fifty euros) for a total of €3 000,00 (three thousand euros)
- At the end of the study (until Day 561) I shall receive €7 212,00 (seven thousand two hundred and twelve euros)

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

If I withdraw from the study for other medical reasons or other reasons not associated with my participation in the study, I shall receive a compensation proportional to the duration of my participation.

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.

If my participation is ended for not respecting the restrictions, I shall be removed from the study, and my compensation amount shall be reviewed proportionally to the duration of my participation.

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) The sponsor has subscribed a no-fault insurance to cover injuries or significant deterioration in health or well-being in connection to my participation in the study.

13. I have been made aware of the reasons for which personal data will be processed and/or transferred as part of the study and of my legal rights concerning these personal data as described in the Participant Information Sheet.

## Signatures:

### *In agreement, the participant:*

_____
Printed name of participant

_____ _____
Signature of participant Date of signature§

§Participant/impartial witness 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 subject to participate. I further confirm that I have handed over a copy of the Information and Consent Leaflet signed by the participant and by me, and that I am willing to answer any additional questions if necessary. I state that I work in compliance with the ethical principles set out in the "Helsinki Declaration" and the Belgian Law of 7 May 2004 concerning experiments on humans.

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
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.

### *Consent for Participant Who Cannot Read:*

The study participant has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

_____
Printed name of impartial witness ‡

_____ _____
Signature of impartial witness Date of signature§

☐ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the participant cannot read.*)

§Participant /impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant cannot read, and who reads the informed consent and any other written information supplied to the participant. *See* Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

# SUPPLEMENT RELATED TO PERSONAL DATA PROTECTION

## Content

This **Supplement related to personal data protection** describes how we will collect, use, and share your personal data. It also describes your rights as data subject of whom personal data are being collected and processed. Your personal data shall be processed in compliance with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data.

## A. What personal data may we collect about you during this study?

The study team and others assisting you with study-related care will collect information related to you (personal data), in the framework of the study. Amongst these personal data; some are sensitive data. These data may include:

- **Information that directly identifies you** such as your name, address, telephone number, e-mail address, date and place of birth, national ID number.
- **Your bank details.**
- **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 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.

## B. Who will use my personal data, how will they use it, and where will it be stored?

Any personal data collected about you during this study will be stored by the study team at your study site. The study team must ensure the confidentiality of your personal data.

Your personal data shall be accessed by:

- The study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People or organizations providing services for, or collaborating with, the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities (including those in other countries); and
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.

The individuals and groups listed above will use your personal data to conduct this study, and to comply with legal or regulatory requirements, including to:

- 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;
- assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests and/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
- answer your personal data protection requests (if any).

The study site will retain your personal data for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the study.

If you provide someone else's personal data (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us. We will only use such personal data in accordance with this informed consent and applicable law.

**C. What happens to my personal data that is sent outside the study site?**

Before the study team transfers your personal data outside the study site, the study site will replace your name with a unique code and remove all information that directly identifies you. We call this "**Coded Information**." The study site will keep the link between the unique code and your personal data confidential, and the Sponsor will not have access to that link. The Sponsor's employees and representatives are required to protect your Coded Information and will not attempt to re-identify you.

Your Coded Information will be used by the following persons:

- The Sponsor and its representatives (including its affiliated companies);
- People and/or organizations providing services to or collaborating with the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or the rights to the product under study;
- Other researchers;
- The IRB or IEC that approved this study;
- Government or regulatory authorities, if necessary;

The above parties may use your personal data for the following purposes:

- **Conducting the study**, including:
  - Examining your response to PF-07275315;
  - Understanding the study and the study results; and
  - Assessing the safety and efficacy of PF-07275315.

- **Complying with legal and regulatory duties,** such as:
  - Ensuring the study is conducted according to good clinical practice;
  - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities;
  - Seeking approval from government or regulatory authorities to market PF-07275315 (it is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research); and
  - Sharing study data with other researchers not affiliated with the Sponsor or the study team (including through publication on the internet or other media). However, information that could directly identify you will not be made available to other researchers.
- **Publishing summaries of the study results** in medical journals, on the internet or at educational meetings of other researchers. You will not be directly identified in any publication or report of the study. However, some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Moreover, journals may require that genetic and other information from the study that does not directly identify you, be made available to other researchers for further research projects.
- **Improving the quality, design and safety** of this study and other research studies.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the study.

## D. How are my biological samples and images handled?

If biological samples or images of you are taken during the study, those samples and images will be handled in the same way as your Coded Data. All samples will be treated as required by law. Sometimes your study site may be unable to remove information that can identify you from your images before sending images to the Sponsor and its representatives.

## E. Can my personal data be used for other research?

Your Coded Information may be used to advance scientific research and public health in other projects that will occur in the future. At this time, we do not know the specific details of these future research projects.

This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources**: Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your Coded Information, which may include:

    - Limited access to Coded Information to specific individuals who will be bound to keep this information confidential and will be prohibited from attempting to re-identify your Coded Information.
    - Use of security measures to avoid data alteration, loss and unauthorized access.
    - Anonymisation of the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
    - Assessment of data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
    - When required by applicable law, verification that the scientific research has obtained the approval of IECs, IRBs, or other similar review groups.

## F. How will my personal data be protected when transferred from the study site to the Sponsor?

Your personal data will be treated in compliance with applicable data protection laws. The Sponsor and Pfizer Clinical Research Unit (PCRU), part of Pfizer SA, are the data controllers of your personal data. The PCRU will be the data controller of your personal data and the Sponsor, will be the data controller of your Coded Information.

Some of the people using your personal data, including your Coded Information, may be based in countries other than those of the European Union (EU) and of the European Economic Area (EEA), including the United States. Data protection laws may be different in these countries. The European Commission has decided that some of these countries provide a level of data protection equivalent to the one available in the EU (the full list of these countries is available at this website: https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en)

The Sponsor and people working with the Sponsor will take steps to maintain the confidentiality of your personal data. If your personal data is transferred by the Sponsor from the EU, EEA, and/or Switzerland to other countries that have not yet been found by European Commission to meet requirements for the protection of personal data, the Sponsor has put in place standard EU data transfer agreements to protect your personal data. Please contact your study team to obtain a copy of these standard data transfer agreements.

## G. What are my data protection rights? Whom may I contact about these rights or any concerns or complaints?

If you wish to exercise any of the rights described below or have concerns about how your personal data is being handled, it is best to contact the PCRU and not the Sponsor of the study. Generally, the Sponsor will not know who you are (by name) because the Sponsor only holds your Coded Information, which does not include your name or other information that can identify you. Please contact the PCRU, the study team representative or PCRU data protection officer, at the following address: Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels, Phone: 0800/99.256 or +32 2/556.70.02; Email: PfizerVolRecruitment@pfizer.com.

- You have the right to 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 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.*
- You have the right to file a complaint with the data protection authority:

  **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

## H. What happens if I do not wish to continue with the study?

As noted in the main 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 and check whether you wish to continue in the study. If the study team is unable to reach you, the Sponsor may use publicly available records about your health to monitor the long-term safety of the study medicine. This will only be done if allowed by the law.

If you stop taking part in the study but do not withdraw your consent for the processing of your personal data, your personal data will continue to be used in accordance with this document and applicable law.

If you decide to withdraw your consent:

- You will no longer be able to participate in the study;
- No new information or samples will be collected about you or from you by the study team.
- The study team may still need to report any safety event about the medicine related to the study that you may have experienced due to your participation in the study;
- Your personal data, including your Coded Information, that has already been collected up to the time of your withdrawal of consent, will be kept and used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of PF-07275315, to satisfy legal or regulatory requirements and/or for any other purposes permitted under applicable data protection laws.;
- Your personal data, including your Coded Information, will not be used for further scientific research. However, if your personal data has been anonymized so that the information does not identify you personally, that information may continue to be used for further scientific research (as described in Section E of this document), as permitted by applicable law; and
- Biological samples that have been collected but not analysed will no longer be used, unless permitted or required by applicable law.

  You have the additional right to request that any remaining samples that have been collected from you as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. The study team will then send your coded request to the Sponsor. In some countries, local laws or regulations may require that your samples be destroyed or de-identified if you withdraw from the study, regardless of whether you specifically make such a request.

  However, we cannot guarantee the destruction of all samples because some of the samples may no longer be traceable to you, they may have been entirely used up, or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your biological samples and any related data.