Protocol Title:	A PHASE 1, RANDOMIZED, SPONSOR OPEN, TWO-PART CROSSOVER STUDY TO ASSESS SAFETY, TOLERABILITY, AND FOOD EFFECT OF MULTIPLE DOSES IN PART 1 AND PALATABILITY OF A SINGLE DOSE OF SISUNATOVIR IN PART 2, IN HEALTHY ADULT PARTICIPANTS
Protocol version	Protocol Amendment 1, 23 December 2022
EudraCT/EU-CT number:	2022-003426-53
Study medicine or study drug:	PF-07923568 (sisunatovir)
Sponsor of the study:	Pfizer Inc.
Study site:	Pfizer Clinical Research Unit (PCRU) Route de Lennik 808, 1070 Brussels, Belgium
Investigator (study doctor):	Laure Mendes da Costa
Emergency contact:	0800 30 019 or +32(0) 2 556 70 03

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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-07923568 (also referred to as "sisunatovir", "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.

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 "Compensation and insurance" on page 17.
- 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 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-07923568 (sisunatovir) will include an estimated amount of 12 participants (hereafter referred to as 'Cohort 1'). However, the study may also enrol an optional cohort of approximately 12 additional participants (hereafter referred to as 'Cohort 2').

This study will take place at the Pfizer Clinical Research Unit (further referred to as "PCRU") in Belgium.

1. Purpose of the study

The study consists of 2 parts.

1. The purpose of Part 1 (for Cohort 1 and Cohort 2) of this study is:

- to assess how your body tolerates the PF- 07923568 (sisunatovir) when receiving multiple oral doses (=safety and tolerability).
- to find out the amount of PF- 07923568 in your blood after you take PF-07923568 with and without food.

2. The purpose of Part 2 (only for Cohort 1) of this study is:

- to assess the palatability of PF- 07923568 mixed with water, infant formula, apple juice or saline. It will inform further development of formulations appropriate for pediatric studies.

2. Legal status of the study medicines

PF-07923568 (sisunatovir) is an orally administered RSV F-protein inhibitor being developed to target viral-host cell fusion for the treatment of adult and pediatric patients with RSV (Respiratory Syncytial Virus).

PF-07923568 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 10 weeks.

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

- A screening examination.
- **Part 1 (Cohort 1 and optional Cohort 2):**
  Period 1 to Period 3: three treatment periods organised of 8 days and 7 nights in the PCRU (from Day -1 to Day 7). The three treatment periods will be separated by an interval of approximatively 7 days.
- **Part 2 (only Cohort 1):**
  Period 4 to Period 7: assessments will occur on the same day and will be performed on Day 7 of Period 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 undergo a questionnaire, 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. More information on COVID-19 measures during this study are included in the additional COVID-19 consent document.

2. 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, 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.

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 be asked to 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 coming to the PCRU.

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:

Periods 1, 2 and 3 (Cohort 1 and optional Cohort 2):

- Physical examination: at admission of Period 1.
- Detection of drugs in urine: at admission of each period
- Triplicate ECG: 29 measurements for each period
- Measurement of supine blood pressure and heart rate: 7 measurements for each period
- Administration of the study medicine (see the section “Treatments administered during the study” page 6).
- Blood and urine samples for laboratory tests: 4 samples for each period (for which you will have to be fasting for at least 4 hours).
- Blood pregnancy test (only for women with childbearing potential): at admission of each period.
- Blood samples to determine the amount of PF-07923568 (sisunatovir): 25 samples for each period
- Blood samples for analysis of biomarkers: 16 samples for each period
- Retained research samples: 2 samples, see section “Retained research sample” on page 12 for details.

Periods 4, 5, 6 and 7 (only for Cohort 1):

- Palatability assessments: 16 completions in total (see the section ‘Specific features of the study” on page 8)

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

The investigator may ask you to come in for additional tests, procedures and assessments, if necessary, to protect your health.

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

4. Treatments administered during the study

The planned treatments are:

COHORT 1

Part 1 (Periods 1, 2 and 3):

- Treatment A: **400 mg** PF-07923568 administered as 8 capsules twice a day (from Day1 to Day 4) and in the morning (Day 5) under fed condition*
- Treatment B: **200 mg** PF-07923568 administered as 8 capsules, twice a day (from Day1 to Day 4) and in the morning (Day 5) under fed condition*
- Treatment C: **Placebo** for PF-07923568 administered as 8 capsules, twice a day (from Day 1 to Day 4) and in the morning (Day 5) under fed condition*
- Treatment D: **400 mg** PF-07923568 administered as 8 capsules, twice a day (from Day1 to Day 4) and in the morning (Day 5) under **fasted condition****

PERIOD / SEQUENCE	Period 1	Period 2	Period 3
Sequence 1	**Treatment A**	**Treatment C**	**Treatment D**
Sequence 2	**Treatment C**	**Treatment A**	**Treatment D**
Sequence 3	**Treatment A**	**Treatment B**	**Treatment D**
Sequence 4	**Treatment B**	**Treatment A**	**Treatment D**

Treatments A, B, C and D will be administered in a random order determined by computer (also called "randomization").

- Periods 1 and 2 are blinded meaning neither you, nor the PCRU staff will know whether you are receiving PF-07923568 (sisunatovir) or placebo. However, the PCRU staff will be able to obtain the study medicine identity if necessary.
- Period 3 is open label meaning you, the investigator and the PCRU staff will be aware of the study drug being given.

The amount of study medication for Periods 2 and 3 are dependent upon the pharmacokinetics analysis in the previous periods and they might be modified if needed.

Part 2 (Periods 4, 5, 6 and 7):

- Treatment E: 50 mg PF-07923568 in 7 mL **water**
- Treatment F: 50 mg PF-07923568 in 7 mL **infant formula**
- Treatment G: 50 mg PF-07923568 in 7 mL **apple juice**
- Treatment H: 50 mg PF-07923568 in 7 mL **saline**

You will receive all 4 treatments (E, F, G and H), alternately one per study period (Periods 4, 5, 6 and 7) given in a randomized order. All the assessments of Periods 4, 5, 6 and 7 will occur on Day 7 of Period 3.

An example of a potential sequence in Part 2:

PERIOD / SEQUENCE	Period 4	Period 5	Period 6	Period 7
Sequence	**Treatment E**	**Treatment F**	**Treatment G**	**Treatment H**

COHORT 2 (optional Cohort)

Part 1 (Periods 1, 2 and 3)

- Treatment I: **maximum of 400mg** PF-07923568 administered as up to 8 capsules twice a day (from Day 1 to Day 4) and in the morning (Day 5) under fed condition* - the dose will be determined after review of Cohort 1 data
- Treatment J: **Placebo** for PF-07923568 administered as up to 8 capsules twice a day (from Day1 to Day 4) and in the morning (Day 5) under fed condition*
- Treatment K: **maximum of 400mg** PF-07923568 administered as up to 8 capsules twice a day (from Day1 to Day 4) and in the morning (Day 5) under **fasted condition**** - the dose will be determined after review of Cohort 1 data

PERIOD / SEQUENCE	Period 1	Period 2	Period 3
Sequence 5	**Treatment I**	**Treatment J**	**Treatment K**
Sequence 6	**Treatment J**	**Treatment I**	**Treatment K**

Treatments I, J and K will also be administered in a randomized order.

- Periods 1 and 2 Neither you, nor the investigator or the PCRU staff will know whether you are receiving PF-07923568 or placebo. However, the PCRU staff will be able to reveal which study drug you have received, if necessary.
- Period 3 is open label meaning that both you, the investigator and the PCRU staff will be aware of the drug being given.

(*) Fed condition, meaning: you will receive the treatment approximately 30 minutes after the start of the meal that will be consumed over approximately 20 minutes.

(**) Fasted condition, meaning: for the Day 1 and Day 5 morning doses, the pre-dose fasting period is 10 hours and post-dose fasting period is a minimum of 4 hours. For all Days 2, 3, and 4 morning doses, the pre-dose fasting period is 8 hours and the post-dose fasting period is a minimum of 1 hour. For evening doses, the pre-dose fasting period is 4 hours, and the post-dose fasting period is a minimum of 1 hour. You cannot drink water 1 hour before and 1 hour after the administration of the study medication.

5. **Specific Features of the study**

Palatability questionnaire - Only for Cohort 1 (Part 2: Period 4 to Period 7)

You will taste PF-07923568 (sisunatovir) 50 mg capsule content in 7 mL of water, saline, apple juice, and infant formula, given in a randomized order. There will be 60 min between each treatment given at each period (Period 4, 5, 6 and 7). This will occur on Day 7 of Period 3

Immediately, 5, 10 and 20 minutes after receiving each treatment (Treatment E, F, G and H) you will have to answer a questionnaire comprising rating scales aimed at qualifying the gustatory characteristics (mouth feel, bitterness, sweetness, sourness, saltiness, tongue/mouth burn and overall liking) of PF-07923568 when administered mixed in water, infant formula, apple juice or saline.

Possible Risks and Discomforts

1. **Possible side effects**

The safety of PF-07923568 has been studied in humans and animals.

In studies in rats and dogs, PF-07923568 was given at various doses up to 28 days. At the high doses administered to rats for up to 14 days, there was evidence of tissue inflammation and/or damage of the bile duct, heart, kidney, the blood vessel of the lungs, and windpipe (trachea). At the high doses administered to dogs, vomiting and loose stools occurred, and there was evidence of inflammation in the gastrointestinal tract (e.g., gall bladder, liver) when treated for up to 28 days. Evidence of reduced size of the thymus was observed at the high dose in both rats and dogs treated up to 28 days. These events occurred in animals that received doses 4 to 33 fold higher than what will be dosed in humans. In the current study, the study drug PF-07923568 is administered at a lower dose and for a shorter duration than what was administered in the animal studies.

The safety of PF-07923568 has also been studied in 201 healthy adult participants in clinical studies. In addition, as of 03 October 2021, 24 pediatric patients hospitalized with RSV infection have received a single dose of PF-07923568. Doses have ranged from 10 to 525 mg in adults. The study drug was overall well tolerated at all doses. The most frequently reported side effects were nausea, diarrhea and abdominal pain in adults who received more than one dose of PF-07923568, and vomiting in children who received one dose. These side effects were mild to moderate, and they resolved without any aftereffects. The vomiting in children occurred when PF-07923568 was administered orally in water, and the vomiting did not happen when PF-07923568 was administered suspended in formula or breast milk together with a sweetened gel. There has been one serious side effect reported, a case of fever of short duration, in a child hospitalized with RSV infection who received a single dose of PF-07923568. The study doctor assessed the event as not related to the study drug.

During clinical studies of PF-07923568 you will be monitored for occurrence of symptoms or side effects. Blood and urine samples will be taken to measure and evaluate for any changes in laboratory test results.

The effects of PF-07923568 on reproduction are unknown. PF-07923568 has not been studied in pregnant or lactating women. Animal studies of PF-07923568 did not indicate harmful effects with respect to pregnancy or embryonal/fetal development. At this time, it is not known whether PF-07923568 can cause harm to the fetus or whether it is secreted in human milk. Therefore, PF-07923568 should not be administered to pregnant women or women who are breastfeeding. An appropriate method of contraception, that is highly effective, is required to participate in this study.

Since the use of PF-07923568 is investigational for the treatment of RSV infection when taken alone or in combination with other medications, there may be other risks or side effects that are unknown. Human clinical and animal studies do not always predict the side effects of experimental medicines that people may experience. There may be rare and unknown side effects, including reactions that may be life-threatening and could result in sickness or death.

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 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.

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

2.1. Blood draws

Blood draws may cause faintness, dizziness, inflammation of the vein (blood vessel), pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.

The total quantity of blood taken during the study will be approximately 340 mL.

The times for taking blood may change. Additional blood samples may be added provided the total volume of 550 mL is not exceeded.

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 such as: dizziness, headache, stomach discomfort, fainting, and/or possibly hypoglycaemia .

2.4. 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 genetic 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. The results of tests on your sample will not be given to you or the investigator.

If you do not agree with genetic testing to be done on your samples, you cannot participate in this study.

3. Contraception, pregnancy and breast-feeding.

3.1. For women:

You may participate in this study, provided that:

- you are between the ages of 18 and 65 years, **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.

If you are considered as being capable of having children and you take part in this study, you must use contraception.

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 and at the start of each study period, you must take a pregnancy test with a negative test result.

You must fulfil one of the following conditions:

- you have had a bilateral tubal occlusion;
- you have a non-hormonal IUD;
- 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.

Non-hormonal contraceptive methods will have to be started at least 14 days before the start of the study and will have to be continued until minimum 28 days after last administration of study medicine intake.

If you are taking hormonal contraceptives or hormone replacement therapy within 28 days of the first dose of study treatment, you cannot take part in this study. Injectable hormone therapy (e.g. DepoProvera®) must be discontinued at least 6 months prior to the first dose of study treatment.

3.2. For men:

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

You must fulfil the conditions below:

- If you have a partner and you are not abstinent, you may take part in this study on condition that:
  - you use condoms during your participation in the study and for at least 28 days following the last administration of the study drug to prevent, among other things, the possible transfer of the study drug through the semen during the study, if your partner is a woman of childbearing potential.
  - In addition to that your female partner will have to use one of the following contraception methods:
    1. IUD or IUS, at least for 14 days before the start of the study;
    2. hormonal contraception, at least for 28 days before the start of the study.
  - Your female partner will not need to use contraception methods as set forth above, if you have had a vasectomy more than six months ago, or if your partner is a woman that is post-menopausal or surgically sterilised.
- if you are abstinent from heterosexual intercourse with a female of childbearing potential as your preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent, you do not have to use additional contraception.

Taking the study drug could bring about an unknown risk for an embryo, foetus or could negatively affect the quality of the sperm. It is important that you tell the investigator or PCRU staff if your partner is pregnant or if you plan to conceive during the study and up to at least 28 days after the last administration of the study drug. You commit to inform your partner about your taking part in this study and the potential risks for an embryo or foetus.

You cannot donate sperm until at least 28 days after the last administration of the study drug.

3.3. Pregnancy follow-up

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 the 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.

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(s)

A 4 mL and a 10 mL blood sample will be collected at Day 1 of Period 1. These samples will be used to study biological substances in your sample(s), including your genes. This will help us learn more about the study drug. and to investigate safety biomarkers.

These samples are called “Retained Research Samples”.

The sample will be held by the sponsor for up to 25 years. Results will not be communicated to you or your general practitioner. In case the investigator learns of incidental findings as part of this study, they will be handled as described in section “Incidental findings” on page 15. The sponsor may share the samples and/or data derived from them with third parties (such as other researchers and collaborators at other institutions and companies) consistent with the uses described above.

Specimens will be stored at a Pfizer-designated facility, which is currently located at 2910 Fortune Circle West, Suite E, Indianapolis, Indiana, 46241 in the United States.

The sample(s) are deemed to be “donation” and 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 investigator 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.

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 before the start of the first dosing, throughout the duration of the study and up to the day of final payment.

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 the screening examination, start of the study and throughout each study period,

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

- 48 hours before the screening examination, start of the study and throughout each study period,

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

- 24 hours before the start of the study prior to dosing 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 until the last day of the last period.

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 outside of the limits for this study of age (18-65 years) or weight (minimum of 50 kg), or Body Mass Index (17.5 - 35 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 you have received treatment that may affect absorption of the medicines (for example a gastrectomy, cholecystectomy).
- 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>

In addition, you may not take part in this study if you have a history of sensitivity to PF-07923568 (sisunatovir) or any of the formulation components.

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;
- carry the "emergency card" with you at all times 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 12 months.

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.

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.

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, or werespectyourprivacy@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	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.

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 medicine or in the event that the Ethics Committee takes a new decision on the study.

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 10.i) of the “Participant Agreement and Consent Form”).

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 or make audio/video recordings 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 medicine 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); and

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, images and/or audio/video recordings, 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, images and/or audio/video recordings 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, meaning that the images shared with others may be identifiable as yours.

The study site will upload your information, including information that directly identifies you, to a designated secure electronic system maintained by a third party engaged by the sponsor. The sponsor and/or the sponsor’s representatives will use this secure system to review and verify study data as they would at the study site. The sponsor is the controller of the information uploaded to this electronic system. Some of these uploaded records will be kept for the period necessary to fulfil the purposes outlined above, as required by applicable law and/or for the maximum period permitted by applicable law on the secure

electronic system. The remaining records that are uploaded will be temporary and removed/deleted from the secure electronic system after the study is over.]

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, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

Yes. The sponsor may use your Coded Information, biological samples, images and/or audio/video recordings, 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 PF-07923568 and drug of the same group work,
- The disease/condition for which PF-07923568 is evaluated in this study, or
- Other diseases and health problem which could benefit PF-07923568 or from related diagnostic tests.

This Coded Information, biological samples, images, and/or audio/video recordings, 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, images and/or audio/video recordings 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, images and/or audio/video recordings (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 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, images, and/or audio/video recordings 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, your family 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, images and/or audio/video recordings 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 (page15).

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 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.

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III PARTICIPANT AGREEMENT AND CONSENT FORM	
Investigator	**Laure Mendes da Costa**

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.
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 and safety biomarkers. The sample will be held in a Pfizer-designated facility for up to 25 years

   Study results will not be communicated to me or my general practitioner, unless in case of incidental findings.

   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**

5. 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.
6. 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.
7. I shall not donate blood during the study, nor for two months before or after the study.
8. I undertake to comply with the study restrictions as they are mentioned under "II. Additional information" (page 13). If a violation of these commitments were confirmed by laboratory tests, I could be excluded from the study.
9. 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.
10. The sponsor confirms that:

    i) I shall receive the sum of **€ 4 525.00** (four thousand five hundred twenty-five 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, 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 reasons unrelated to 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) A provision has been made for no-fault insurance to cover research injury liability of the sponsor established in relation to the study.

11. 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, but you may be unable to take part in this study if you don't. 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.

12. 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 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

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.

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.

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.

Genotyping: The proteins that make up the machinery of the human organism are produced from chromosomes. The place on a chromosome that identifies a protein is called a gene. The analysis of a gene is called «genotyping».

Hypoglycaemia: low blood sugar concentration.

Hysterectomy: Ablation (surgical removal) of the uterus.

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 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.

RSV (respiratory syncytial virus): respiratory virus that infects the lungs and breathing passages

RSV F-protein: also known as ‘RSV fusion protein’, a protein on the surface of RSV virus which plays a role in the initial phase of infection.

Saline: a solution of salt in water

Thymus: a small gland that makes immune cells to fight infection