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Participant Information Sheet and Informed Consent Form

Title of Study	A double-blind, placebo-controlled, randomized, 18 month Phase 2a study to evaluate the efficacy, safety, tolerability and pharmacokinetics of oral UCB0599 in study participants with early Parkinson's disease
Short Title	A double-blind, placebo-controlled, randomized, Phase 2a study with oral UCB0599 in study participants with early Parkinson's disease
Protocol Number	PD0053
IRAS ID	1003518
Sponsor	UCB Biopharma SRL
Study Doctor	Dr Emer MacSweeney
Participant ID	

Introduction

You are being invited to participate in a clinical research study initiated, managed, and financed by UCB Biopharma SRL (UCB), the Sponsor of this study (hereafter referred to as Sponsor). Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet and Informed Consent Form will provide you with essential information about this study and your rights as a clinical research study participant so that you can make an informed decision about your participation.

Your decision to participate in this study is entirely voluntary. You will not lose any benefits which you would otherwise be entitled to if you choose not to participate. Your normal clinical care will not be affected if you chose not to participate. In addition, you may withdraw from the study at any time. You will be informed in a timely manner, if any relevant new information about this study medication or this study becomes available that may alter your willingness to continue to participate.

Why Have I Been Invited?

You are being invited to participate in this research study because you are living with Parkinson's disease (PD). PD is a slowly progressive nervous system disorder that affects movement. This means that it causes problems in the brain and symptoms gradually get worse over time. In patients with PD, brain cells (also known as neurons) that are involved with movement, stop working or die (a process known as neurodegeneration). The loss of these brain cells is seen as the major cause of PD symptoms. In people living with PD, symptoms appear over time and slowly get worse. The most common symptoms are slowness of movement, involuntary shaking, and stiffness of muscles. These types of symptoms related to movement are called motor symptoms. There are also non-motor symptoms, such as loss of smell, depression, constipation (infrequent bowel movements and/or difficulties with passing stool), and sleep disorder may occur early in the disease.

What is the Purpose of the Study?

The purpose of this study is to help determine if UCB0599 (hereafter referred to as the study medication) can slow the progression (worsening) of PD. Due to the way the study medication works in the brain, it is not expected to provide immediate relief of PD symptoms, but it may be able to delay their start or reduce how bad the symptoms get in the long term by protecting brain cells.

The main questions to be answered in this study are:

1) What is the effect of the study medication on the worsening of clinical symptoms of PD?
2) What side effects did the participants have during the study?
3) How well were participants able to tolerate side effects caused by the study medication?
4) How does the body handle or metabolise (process) the study medication (pharmacokinetics [PK])?

The study medication is an investigational drug, which means that it is still being tested, and has not yet been approved for treatment by any health authorities worldwide. The Sponsor has conducted five Phase 1 clinical studies in healthy elderly people, both with or without PD. It has shown an acceptable safety and tolerability profile for further testing in patients living with PD.

Approximately 450 patients living with PD will take part in this study. The participants will receive treatment with one of two doses of the study medication or placebo (a dummy drug that looks like the study medication but contains no active drug substance). The study will be conducted in several countries in Northern America and in Europe.

What Will Happen to Me if I Take Part?

The study consists of three periods:

1. Screening Period (3-6 weeks)
2. Treatment Period (18 months)
3. Safety Follow-up (SFU) Period (1 month)

The 18-month Treatment Period will be double-blinded, which means neither you nor the study doctor will know whether you are receiving the study medication (and in which dose) or placebo. However, this information is readily available in case of an emergency.

Throughout the study, you will attend study site (onsite) visits and you will also have the option to have home (remote) visits. During onsite visits, you will meet the study doctor and the study staff at the study site. For remote visits (in your home), you will be given a tablet computer with a pre-installed application (App) that allows secure video conferences, phone calls, and a web link as a way of communicating with the study doctor and the study staff. The goal of this so-called “telemedicine” system is to make it easier for participants to take part in the study as they will have to come to the study site less frequently. You will also be asked to answer study questionnaires (described later in this document) using this App. At the study site, you will be thoroughly trained on how to register yourself and how to use the tablet computer and the App (computer skills are not required).

During the home visits, a mobile healthcare personnel (e.g., a qualified nurse) will monitor your health status, support you with any questions and assist the study doctor during the video conferences. The mobile healthcare personnel will perform physical and neurological examinations, vital sign assessment, ECG, blood/urine sampling, and urine pregnancy test under the instruction of the study doctor.

Considering the Coronavirus Disease 2019 (COVID-19), please follow the visit schedule below as much as you can. If you are unable to come to the study site, and if you agree to it, the study doctor may contact you directly via telephone and/or video conference calls. If you visit another facility for a medical issue (or have to switch study sites for a COVID-19-related reason), the study doctor may contact your treating doctor to obtain the details of your condition and your participation.

You will be monitored for and encouraged to report any signs and symptoms of COVID-19.

In order to reduce the possibility of COVID-19 transmission you should:

- Follow local requirements for reduction of exposure while outside the study site and in the community.
- Follow study site requirements for reduction of exposure while at the study site or when interacting with the study staff.

There are no restrictions on COVID-19 vaccination during your participation in this study and you are free to receive COVID-19 vaccination as per the local or national guidance/regulations.

The study medication is not expected to pose an additional risk of complications or poor prognosis of COVID-19.

Some of the assessments performed during the remote visits may be conducted by the healthcare personnel. The healthcare personnel and study doctor will discuss all observations and findings during the remote visits. Any observation by the healthcare personnel will be discussed with the study doctor during the video communication part of the remote visit. In case an observation requires follow up at the study site, an unscheduled visit will be performed. Also, in case a healthcare personnel is not available to

perform a scheduled remote visit, e.g., due to COVID-19 related contact and transportation restriction or other circumstances, a remote visit may be changed to a study site visit. In addition, study site visits can be changed to remote visits.

Screening Period (Visit 1 and Visit 2)

At Visit 1, the study doctor will explain the study and answer any questions you may have. Before any tests and procedures are performed, you will be asked to read and sign this Participant Information Sheet and Informed Consent Form (E-signing will be acceptable, if allowed in your country. This process will be explained to you by the study doctor or the study staff).

During the Screening Period, the study doctor will determine if you could be a good candidate for this study. It is very important that you inform the study doctor about any current and past medications, or any medical procedures you have received, especially if it is related to your PD medical history. You must also tell the study doctor of any allergies that you may suffer from, as per your best knowledge, to help them to assess the risk of an allergy to any component of the study medication.

During the study, you will be offered to use a wearable sensor called “Study Watch”, which can measure your movements, heart rate, and some other body functions when worn on your wrist. If you consent to the use of the Study Watch, you will need to become familiar with it and regularly perform guided movements of your fingers, hands, and legs. The Study Watch is used for research purposes only. It does not guide diagnosis or treatment. It is optional, if you don’t want to use it you will not be placed at any disadvantage.

Treatment Period (Visits 3-15)

At Visit 3, the study doctor will review the test results from the Screening Period. If the screening procedures show that you are eligible for the study, and you choose to take part, then you can join the study. You will be given a study participant identification card and you will be assigned to 1 of 3 treatment groups (360mg of the study medication per day, 180mg of the study medication per day or placebo). You will be assigned to one of the three treatment groups by chance (like flipping a coin). The 180mg per day treatment group will only be implemented at a later stage of the research study. That means, you may have a 50% chance of receiving either the study medication or placebo, or you may have a higher chance of receiving the study medication (though in the lower dose) than placebo, depending on the status of the trial. Neither your doctor nor anybody else involved in the study can decide which group you are in, and they will not be able to tell you which group you were in until after the study is over. This procedure (called blinding) serves to better distinguish possible effects of the study medication from other changes in your wellbeing (e.g., physical activity or a healthier lifestyle). Regardless of whether you receive the study medication or placebo, you will undergo exactly the same assessments and procedures. The study medication (360mg or 180mg) or placebo will be given to you as capsules. You will take two capsules twice per day, approximately 12 hours apart. During the Treatment Period, you will come to the study site for study assessments at Visit 3, Visit 5, Visit 6, Visit 8, Visit 9, Visit 10, Visit 11, Visit 12, Visit 13, Visit 14 and Visit 15. Visit 4 and Visit 7 may be conducted as remote visits at home or as clinic visits.

In case you need to stop the treatment with the study medication or placebo for safety reasons, we will still ask you to remain in the study (without receiving study medication or placebo) and attend all the remaining study visits along with the procedures. This is to make sure that any of your safety issues resolve and that you are provided with proper medical care. These visits will also provide important information on your disease and health status.

If you leave the study before completing all the visits, you will be asked to come for a final End of Treatment [EOT] visit, and to return 30 days after the last dose of the study medication or placebo for a Safety Follow-up Visit. Please ask the study doctor if you need further information.

If you complete the whole 18-month Treatment Period, you will have the option to take part in a different study called an Open Label Extension (OLE) study; more information is given in the “What Happens When the Research Study Stops?” section.

Safety Follow-up Visit (Visit 16)

If you do not qualify for, or choose not to enter the OLE study, you will be followed up for approximately 30 days after your last dose of the study medication or placebo and come to the study site for the Safety

Follow-up Visit. This visit will be performed at the study site or at your home. After the Safety Follow-up Visit, the study will be over for you.

The schedule of visits, which states the study assessments to be performed at each visit is provided for your information in the table below. Assessments or procedures that will be performed at each visit are indicated with a checkmark (X). Details of the procedures, assessment, and questionnaires are provided after the table.

You can ask the study doctor if you have any questions about any information listed in the table below.

Schedule of Visits

Period	**Screening**		**Treatment Period**													**SFU**
Visit (V)	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**	**V13**	**V14**	**V15**	**V16**
Day (D)/Month (M)	3-6 weeks before Baseline	2-3 weeks before Baseline	Baseline D0	D10	M1	M2	M3	M4	M6	M8	M10	M12	M14	M16	M18 End of Treatment	M19 End of Study
Study site (SS) / Home ( )	**SS**	**SS**	**SS**	**SS/**	**SS**	**SS**	**SS/**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS/**
Procedures, assessments, and questionnaires																
Questions about your personal information, disease, medical condition, and past medications. Height measurement.	X															
Questions about prior or ongoing medications, or procedures you have undergone or are currently undergoing, and questions about your well-being.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review of your continued willingness to participate in the study and the study criteria				X	X	X	X	X	X	X	X	X	X	X	X	
Physical and neurological examination. Vital signs and weight measurements	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questionnaires related to your disease, and quality of life	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Period	**Screening**		**Treatment Period**													**SFU**
Visit (V)	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**	**V13**	**V14**	**V15**	**V16**
Day (D)/Month (M)	3-6 weeks before Baseline	2-3 weeks before Baseline	Baseline D0	D10	M1	M2	M3	M4	M6	M8	M10	M12	M14	M16	M18 End of Treatment	M19 End of Study
Study site (SS) / Home ( )	**SS**	**SS**	**SS**	**SS/**	**SS**	**SS**	**SS/**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS/**
Procedures, assessments, and questionnaires																
Optional participant experience survey			X												X	
United Parkinson's disease Rating Scale of the Movement Disorder Society assessments (MDS-UPDRS)	X		X			X		X	X	X	X	X	X	X	X	X
Blood test[1]	X[2]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine sampling	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test for participants who are able to become pregnant only[3]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Brain imaging (MRI, DaT-SPECT)		X[4]										X			X	
Cerebrospinal fluid (CSF) may be collected by lumbar puncture (optional)		X										X			X	
12-lead electrocardiogram (ECG)	X	X	X	X	X	X	X		X		X	X		X	X	X
The study medication or placebo will be given to you			X		X	X		X		X		X	X		X	

Period	**Screening**		**Treatment Period**													**SFU**
Visit (V)	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**	**V13**	**V14**	**V15**	**V16**
Day (D)/Month (M)	3-6 weeks before Baseline	2-3 weeks before Baseline	Baseline D0	D10	M1	M2	M3	M4	M6	M8	M10	M12	M14	M16	M18 End of Treatment	M19 End of Study
Study site (SS) / Home (📱)	**SS**	**SS**	**SS**	**SS/📱**	**SS**	**SS**	**SS/📱**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS**	**SS/📱**
Procedures, assessments, and questionnaires																
Study Watch and Study Hub familiarisation		X														
Perform motor examinations with the Study Watch on, under observation by the study doctor[5]			X			X		X	X	X	X	X	X	X	X	
Perform virtual motor exams with the Study Watch on at home, without observation by the study doctor[5]		X Daily	X (daily for 2 to 3 weeks, then weekly)													
Return the Study Watch and Study Hub to the study staff[5]												X			X	

Baseline (Day 0); SFU=Safety Follow-up;

📱Telemedicine video call with the study doctor while mobile healthcare personnel visit you at home to monitor your health status, support with any questions, and assist the study doctor during the video call who is supervising a remote visit at your home. The mobile healthcare personnel will perform physical examinations under the instruction of the study doctor.

1 Blood samples include collection of genetic material.
2 You will be asked to fast (avoid consumption of food and liquids, besides water) for 8 hours before blood tests at Visit 1.
3 Your blood will be collected for pregnancy testing at Visit 1. At all other visits, your urine will be collected for pregnancy testing.
4 Only if you don't have an adequate DaT-SPECT scan within the previous 3 months before Screening Visit 1
5 Applicable only if you are wearing the Study watch

Study procedures, assessments, and questionnaires

Physical and neurological examinations: These will be performed by the study doctor or mobile healthcare personnel. An assessment of general appearance; ear, nose, and throat; eyes, hair, and skin; and assessments of the cardiovascular, respiratory, gastrointestinal, musculoskeletal, and hepatic systems. A selected assessment of general neurological status (level of consciousness, mental status, speech), cranial nerves, reflexes, motor system (general motor status, muscle strength, muscle tone), coordination/cerebellar function and sensation will also be performed.

Vital signs: Blood pressure, heart rate, body temperature, and breathing rate will be taken before blood collection. When your blood pressure is taken, an inflatable cuff will be placed on your arm and a machine will measure your blood pressure and heart rate after you have been lying down for 5 minutes and while standing up.

Brain scans or brain imaging: Magnetic resonance imaging (MRI) is a type of scan that uses magnetic fields and radio waves to take pictures of the inside of the head and/or body. MRI scans will be conducted at Visit 2 only if you have not had an MRI scan within 6 months before Visit 1. Single photon emission computed tomography (DaT-SPECT) is a tool used to confirm the diagnosis of PD. DaT-SPECT is a specific type of imaging technique that helps to look at cells in the brain that are important for the action of dopamine (a brain chemical) in the brain. It involves receiving an injection that contains a small amount of a radioactive substance and will be conducted at Visit 2 (only if you don't have an adequate DaT-SPECT scan within the previous 3 months before Screening Visit 1), Visit 12, and Visit 15. Both of these two tests may assess your PD status or help to exclude other conditions. These procedures are explained in more detail in section 4: "Potential Risks and Discomforts" of this Participant Information Sheet and Informed Consent Form.

Cerebrospinal fluid (CSF) samples (optional): If you consent, a small amount of CSF, which is the fluid that surrounds your brain and spinal cord will be collected at Visit 2, Visit 12, and Visit 15 by lumbar puncture (also known as, spinal tap). CSF will be used to test for biomarkers. Biomarkers are compounds in your body that can be used to tell if you suffer from a certain disease and how you may respond to treatment. Each individual CSF sample will be no more than 12mL (approximately 2.5 teaspoons). To have a lumbar puncture, you will be asked to lie on your side and curl up, with your knees pulled up towards your chest. You will be asked to keep as still as possible during the lumbar puncture. A thin, hollow needle will then be inserted between two bones in your lower back. Prior to the lumbar puncture, a local anaesthetic (medication that makes you lose sensation in a certain area of your body) may be applied to numb the area. A lumbar puncture will take approximately 30 minutes. You will be asked to lie flat for approximately 1 hour after the lumbar puncture. You will be able to go home the same day but you won't be able to drive yourself home. CSF sampling will be done after all other assessments of a given visit have been performed. Lumbar puncture is an optional procedure. If you agree to participate in the lumbar puncture specifically, then the first two lumbar punctures (Visits 2 and 12) will be required, and you can again decide whether or not to complete the third (Visit 15) lumbar puncture. CSF samples will be used to improve our understanding of PD and to understand how biomarkers may affect response to or be affected by the study drug during treatment of PD. All collected biomarker samples may also be used for research purposes focusing on method and assay development (assays are used for measuring biomarkers of interest) and its validation (i.e., making sure the assay can accurately measure biomarkers of interest).

ECG: An ECG is a test that assesses the electrical activity of your heart by putting small sticky patches on certain areas of your body while you are lying down. The study staff may need to clip/shave small patches of your hair in these areas. The patches are connected to wires which are then connected to a machine which will interpret the electrical activity of your heart. Both female and male participants must undress from the waist up in order to ensure correct ECG recording.

Blood tests: Blood samples will be taken from a vein in your arm or hand during the study. Blood maybe taken using a needle or a cannula (flexible plastic tube) inserted in a vein in your arm. This minimises the use of needles, though sometimes (if the cannula becomes blocked) a new cannula may need to be inserted or the use of a needle may be necessary. Blood tests will be taken for:

Routine safety laboratory examinations (including tests to monitor function of the liver) and testing items related to blood clotting (except Visit 2).

Pregnancy testing (for participants who are able to become pregnant) at the Screening Visit.

Testing for Hepatitis B and C and the Human Immunodeficiency Virus (HIV) at Visit 1. Hepatitis B and C are viruses that can damage the liver. HIV is the virus that can cause the Acquired Immunodeficiency Syndrome (AIDS) if left untreated. If you have positive results for hepatitis or HIV, you will not be able to participate in this study, and the result will be reported to health authorities as per local requirements.

Blood sampling to determine the amount of the study medication in your body (PK) at Visits 3-6, Visit 8, Visit 10, Visit 12, Visit 14, and Visit 15. Two blood samples must be collected, one immediately prior to intake of the study medication or placebo and one sample from 1 to 6 hours after intake of the study medication or placebo.

Biomarker (including genetic biomarker) analysis: your biomarker samples (including genetic biomarkers) will be collected at Visit 2, Visit 12 and Visit 15 (in case the visit is scheduled before 11:00am, you will be asked to take your study medication during the study site visit after the blood sample is collected). They will only be used to improve our understanding of PD and to understand how biomarkers may affect response to or be affected by the study medication during treatment of PD. All collected biomarker samples may also be used for research purposes focusing on method and assay development (assays are used for measuring biomarkers of interest) and its validation (i.e., making sure the assay can accurately measure biomarkers of interest). You must consent to this biomarker sampling in order to be able to participate in this study.

Testing for SARS-CoV-2, the virus that causes COVID-19, will be conducted at any point during the study if the study doctor believes there is a possibility you have COVID-19. This is an optional test. If you have a positive result for SARS-CoV-2, you may still be able to participate in this study if the study doctor believes continued participation is in your best interests, however the result will be reported to health authorities as per local requirements.

NOTE: Repeat or unscheduled samples may be taken for safety reasons or for technical issues with the samples. The maximum amount of blood collected during the study, including any extra assessments that may be required, will not be more than 50mL (approximately 4 tablespoons) at any visit and will not be more than 500mL (approximately 34 tablespoons) over the duration of the study.

Urine sampling for:

Routine laboratory examinations (except Visit 2).

Pregnancy testing (for participants who may be able to become pregnant) at all visits except Visit 1. Pregnancy testing at Visit 3 will be performed before study medication is given.

Testing for alcohol and drugs-of-abuse at Visit 1.

Home visits: Vital signs and weight will be measured, physical and neurological examinations will be done, and blood and urine samples will be collected, and ECGs will be conducted by healthcare personnel during remote visits.

United Parkinson's Disease Rating Scale of the Movement Disorder Society (MDS-UPDRS): The MDS-UPDRS assessments will be done at all visits except Visit 2, Visit 4, Visit 5 and Visit 7. The MDS-UPDRS scale is used to measure motor and non-motor symptoms of PD and how these symptoms impact activities of daily living.

Questionnaires:
You will be asked to complete a questionnaire called the Columbia Suicide Severity Rating Scale (C-SSRS) at all visits except for Visit 2. The study staff will ask you about how you are feeling mentally and if you have had thoughts of hurting yourself. The C-SSRS will take 10 to 15 minutes to complete.

Other PD questionnaires to measure your symptoms, severity, movement, activity, mental and physical fatigue, anxiety, and depression symptoms. These questionnaires will be completed at Visit 1, Visit 3, Visit 4, Visit 6, Visit 8-12, Visit 13, Visit 14 and Visit 15. You will be either asked to complete some of these questionnaires at home before indicated onsite visits, or you will be asked to complete these questionnaires at the study site before any other assessment is done.

Study Watch: If you consent, you will be provided with two devices for use in this study during Visit 2, the Study Watch and the Study Hub.

The Study Watch is a non-medical, investigational (not approved by any regulatory authority, such as the Medicines and Healthcare products Regulatory Agency (MHRA), monitoring device made by Verily Life Sciences (previously, Google Life Sciences). The Study Watch will collect digital information on your physical indicators, such as movements, heart rate, and some other body functions while worn on your wrist. The Study Watch will not track or record your location.

The Study Hub is a device that will charge your Study Watch and send the data stored on your Study Watch by mobile signal to the Sponsor. This data is coded so you cannot be identified directly and is stored within the European Union for up to 25 years.

You will be asked to wear the Study Watch for up to 23 hours per day, and place the Study Watch in the Study Hub for about 1 hour each day to charge the Study Watch and upload collected data.

It is important that you wear the Study Watch on the same wrist throughout the study.

You will be provided with instructions and training on all tasks and the function of the Study Watch at Visit 2. While wearing the Study Watch, it will collect data daily for 2 to 3 weeks, then weekly. The use of the Study watch may still be started during the treatment period until Visit 8, in case the watch could not be handed out during screening or consent to its use was given after the Screening Period. The Study Watch will guide you through a series of “virtual motor exams”, which are very similar to the exams done on your regular study visits but do not require the study doctor or healthcare personnel to observe.

You should only perform virtual motor exams if you feel you are able to do so safely. If you do not wish to perform an individual task or all tasks, you will be able to dismiss the task(s) on you Study Watch. The Study Watch will be finally returned to the study site at Visit 15 or earlier in case of early study termination.

What Will I Have to Do?

As described before, it is very important to be able to assess the study medication adequately. Make all efforts to attend each study visit as agreed. If you cannot attend at the agreed time and day, please contact the study doctor or other study staff and arrange for another day or time.

Make sure you complete the questionnaires as instructed.

Be honest about your past medical history. As with all medications, there is a risk that a rare or previously unknown side effect will occur, and we cannot rule out the possibility that an unknown side effect may be life-threatening. Please be aware that many medications can cause a serious allergic reaction in certain individuals. For example, penicillin and even aspirin can be life-threatening to some people. You should not take the study drug if you are allergic to any of the ingredient in the capsule.

Give truthful answers to the questions the study doctor or other study healthcare providers ask you.

Notify the study doctor in advance if you plan to undergo any other medical treatment during this study.

You are free to change your lifestyle while participating in this study. Please inform the study doctor of relevant changes (e.g. retirement, start of physical therapies/exercises etc.).

There are medicines that must not be used during the study. The study doctor will check that you are not taking them before you enter the study. Thus, it is important you tell the study doctor before you change any medication because you might start taking medication that is not allowed in this study and this could put your health at risk. You should also contact the study doctor upfront before you take any new

medication, even if another doctor prescribes it or tells you to change doses of your established medications.

You must not take any drugs of abuse or recreational drugs during the study unless the drug is used to treat a chronic, stable condition. This could lead to unpredictable risks, which can seriously damage your health.

You should not eat or drink grapefruit-, starfruit- or pawpaw-containing products within 72 hours (3 days) before you start taking study medication and until the end of the study.

You should not have donated or received 1 or more units (450ml [approximately 30.5 tablespoons]) of blood within 30 days prior to first receiving study medication or placebo or have donated plasma or platelets within 14 days prior to first receiving study medication or placebo .

Notify the study doctor immediately and seek treatment in accordance with the direction of the study doctor if you suffer any injury or unexpected reaction to the study medication.

You must follow the contraception requirements as applicable that are described in this consent form.

If you consent to the use of the Study Watch, you will have to clean it often to remove any sweat that may build up on it.

You will be provided with an identification card which says that you are taking part in this study. Please carry this card with you at all times, and show it to any relevant doctors or nurses. Please return the card at the end of the study

Expenses and Payments

You will not be compensated for taking part in this study. You may receive compensation for necessary travel costs and meal expenses for this study where reasonable and appropriate.

The Study Hub operates on its own mobile connection and will not increase the costs of your own mobile service.

Participation in the study might affect any insurance cover that you may have (e.g. travel insurance, protection insurance (life insurance, income protection, critical illness cover) and private medical insurance). You may wish to seek expert advice on these issues, where necessary.

What are the Alternatives for Diagnosis or Treatment?

The study medication or placebo are not expected to provide immediate relief to any PD symptoms that you currently have or that will develop during your study participation. This study aims to prove that the start of progressively severe symptoms may be delayed under treatment with the study medication when compared with placebo. As such, the timepoint when you start symptomatic treatment is of major interest in this study, and it may lead to study failure if symptomatic treatment is started very early.

Nevertheless, if the need for treating your PD symptoms arises during the study, levodopa would be prescribed by the study doctor as your first line of treatment. The use of levodopa represents the standard of care in many countries, including in the United Kingdom. You would take levodopa in addition to the study medication or placebo. In case levodopa is not well tolerated by you or is not sufficient in treating your symptoms, the study doctor will discuss an alternative treatment with you.

If you start to receive levodopa or any other alternative treatment as mentioned above over the study observation period, you will be asked not to take the medication for at least 12 hours prior to any visit and to bring the medication to the study site.

Starting the treatment of PD symptoms will not lead to your withdrawal from the study, unless you request it.

If you decide not to participate in this study, there are several other treatments available, including medications already on the market. The study doctor will be able to provide additional information to you about these medications.

What are the Possible Risks and Disadvantages of Taking Part?

What are the Side Effects of any Treatment Received When Taking Part?

The study medication being tested may cause some side effects and possible discomforts. You may experience none, some, or all of those given below because medicines and their possible side effects can affect individual people in different ways. Studies with new investigational study medications generally have the risk that you may experience side effects that are currently unknown and unforeseeable.

Based on clinical research studies conducted so far, a total of 98 study participants were given the study medication at doses similar to the higher dose used in this study (360mg). Common side effects (1 to 10 out of 100 persons treated, less than 10% of patients) observed in study participants in previous studies are listed as follows:

- Headache
- Feeling sleepy or lacking in energy
- Sleepiness or dizziness
- Involuntary muscle contractions
- Physical weakness or tiredness
- Low or increased blood pressure
- Allergic reaction (to study medication)
- Hives
- Lip swelling
- Increased or decreased appetite
- Shingles
- Difficulty seeing clearly
- Frequent loose bowel movement or constipation
- Indigestion or stomach pain
- Frequent urination
- Damage to the kidney
- Cough

Drug hypersensitivity:

The most serious side effect(s) that have happened in study participants who have taken the study medication in other research studies were hypersensitivity (allergy-like) reactions. These allergy-like reactions typically included itching, skin rash (redness, swollen patches or hives) and swelling of hands, feet, lips, or tongue. When severe, hypersensitivity (allergy-like) reactions may cause difficulty breathing, low blood pressure and could be life-threatening, if not treated. So far, moderately intense but not severe allergy-like reactions have occurred in study participants taking the study medication. In these cases, moderately intense but not severe allergy-like reactions started within a month after starting treatment with the study medication. However, it cannot be excluded that an allergy-like reaction may appear at any time during the study.

It is very important that you contact the study site immediately after you notice any kind of rash, swelling, breathing difficulty, or allergy-like reaction during the study, even if you do not think it is hypersensitivity or an allergy-like reaction. Seek medical advice from the study site as soon as possible and do not take any study drug until you have contacted the study site and discussed your symptoms with the study doctor.

In order to help evaluate a possible allergy-like reaction to the study medication, the study doctor may ask you for your consent to take pictures of skin reactions and/or swelling. If you consent to have pictures taken, the study staff at site will ensure that you as a person cannot be identified by characteristic tattoos, sections of you face, or other identifiable characteristics. If you are asked to provide pictures (e.g., taken by yourself at home), you should also avoid sharing pictures showing characteristics that might help identifying you as an individual. The study doctor will advise you on data protection requirements.

Additional possible side effects:

Researchers do not know all of the side effects that could happen. More details about possible risks are provided below.

There is good scientific support to suggest that the study medication could be an effective treatment of PD. However, currently there is limited knowledge about what side effects may occur. Potential side effects are listed below, although other side effects may also occur.

- Heart effects: Slower heart rate, faster heart rate.
- Gastrointestinal effects: Vomiting (being sick and throwing up).
- Damage to the liver.

- Damage to the kidneys.
- Damage to the muscles.

To monitor for potential side effects of the study medication, the following safety measures will be implemented:

- Your blood and urine samples will be taken regularly to check whether your liver, kidney, or body organs are in good health. If any abnormality is found in your liver, kidney, or other organs, the study doctor will ensure appropriate treatment is provided to you. You may need to stop treatment with the study medication or placebo for safety reasons, if pre-determined criteria for liver function tests are met.
- During the study, the study doctor will carefully perform a complete physical examination, including neurological examination, to detect any side effects on your skin, nervous system, muscular system, or other body organs. If you develop any abnormality in physical and/or neurological examination, the study doctor will ensure appropriate treatment is provided to you.
- Your blood pressure will be measured regularly, and ECGs will be performed regularly to check that your heart and vessels are in good health. If you develop any abnormality in blood pressure or ECG, the study doctor will ensure appropriate treatment is provided to you.

Drug-drug Interaction (i.e. where one drug affects another drug you are taking):

You must notify the study doctor of any other medication you are taking. Do not start taking other medication during the study before informing the study doctor as the study medication may have an impact on how some other medications are working.

Overdose:

If you have taken more of the study medication than you should have, contact the study doctor immediately.

Potential risks of the study procedures:

Blood tests:

The taking of a blood sample may cause some slight discomfort and bruising, and there is a risk of infection. Other risks, although rare, include dizziness and fainting. In very rare cases, nerve damage may occur.

Electrocardiogram (ECG):

The ECG is of little or no risk. The sticky pads may cause some local skin irritation and may be uncomfortable to remove.

Blood pressure:

You may experience mild discomfort in your arm while the cuff used to measure your blood pressure is inflated.

Magnetic Resonance Imaging (MRI; if not done before with an available report):

The procedure does not use X-ray radiation. There have been no ill effects reported from exposure to the magnetic or radio waves used in MRI. However, it is possible that harmful effects could be recognised in the future. A known risk is that the magnet could attract certain kinds of metal that may cause injury to you. You will be asked about metal within your body (this includes, for example, body piercings, or a pacemaker). In addition, the MRI scanner makes a loud, knocking noise that in very rare and extreme cases could affect hearing ability. The study staff will provide you with ear plugs or other protection for your hearing while in the MRI scanner. Lying in the small confined area may case you some discomfort or anxiety. The study doctor may choose to give you medication to help you relax during the procedure.

DaT-SPECT:

If you take part in this study you will have the DaT-SPECT procedure. Some of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you to about 0.06%.

Side effects can include headache, dizziness, increased appetite and an unusual feeling under the skin.

Cerebrospinal fluid sample (CSF) sample by lumbar puncture:

The most frequent side effect of lumbar puncture is a severe headache that may be accompanied by feeling sick, being sick, and dizziness. You will be asked to lie flat for approximately 1 hour after the lumbar puncture to minimise the risk of developing a severe headache. The needle insertion may cause some slight discomfort and bruising, and there is a risk of infection. While extremely rare, the procedure may also cause bleeding into the fluid surrounding the spinal cord and brain or an abnormal movement of your brain inside your skull, either of which can be fatal.

Study Watch:

The Study Watch contains sensor electrodes (small metal bits that measure your movements, heart rate, and other body functions) that are made of stainless steel which contains a small amount of nickel. If you have severe allergies to nickel or metal jewellery, you should not wear the Study Watch, and inform the study doctor about this.

Other risks and discomforts related to the Study Watch include, skin discomfort (for example, itch, dry skin, redness, rash), discomfort caused by wearing the Study Watch, or potential injury caused by shattered glass. See provided Study Watch Operator's Manual for more details.

There may be side effects that are not known at this time. If you experience discomfort or side effects from wearing the Study Watch, please remove it and contact the study team.

The Study Watch's charging dock contains small magnets that could potentially affect implantable medical electronic devices such as cardiac pacemakers, implantable defibrillators, and medical pumps. The device (while not worn on the wrist), the charging dock, and the Study Hub should be kept at least 15 cm (6 inches) from any implantable device. This information is also relevant for people living in the same place as you. If you are wearing another kind of implantable device, including cardiac pacemakers, pumps, and implantable cardioverters, you are excluded from wearing the Study Watch, but may participate in the main study.

Harm to the Unborn Child

Because the safety of the study medication during pregnancy and breast-feeding is not known, women who are pregnant or are nursing may not participate in this study. Women who are able to become pregnant will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the study.

Female participants:

- Be of non-childbearing potential (i.e., be surgically sterilised or have had no menstrual bleeding (postmenopausal) for at least 12 months and confirmed by a blood test).
- If of childbearing potential:
    - Agree not to become pregnant during the participation in the study and for at least 1 month after the last dose of the study medication or placebo.
    - Must have a negative result of a blood pregnancy test before the Treatment Period.

- If heterosexually active, agree to consistently and correctly use a form of highly effective birth control method as described below.

Male participants:

Male participants with female partners of childbearing potential must agree to use the following contraception during the Treatment Period and for at least 3 months after the last dose of the study medication or placebo (as you will not know whether you are receiving the study medication or placebo during the study).

- Agree to use a male condom plus female partner use of a contraceptive method with a failure rate of less than 1% per year, as described below.
- Refrain from donating sperm for the duration of the study and for 3 months after the last dose of the study medication or placebo.
- Are abstinent from penile-vaginal intercourse as their usual and preferred lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent.

Highly effective methods of contraception include:

- Oral (pill), intravaginal or transdermal combined (oestrogen and progestogen containing) hormonal contraception.
- Oral or injectable progestogen only hormonal contraception.
- Implantable progestogen only hormonal contraception (Intrauterine device or intrauterine hormone-releasing system).
- Bilateral tubal occlusion, intrauterine device or intrauterine hormone-releasing system.
- Vasectomised (sterilised) partner, provided the partner is the sole sexual partner and the absence of sperm has been confirmed.
- Sexual abstinence, if this is the preferred and usual lifestyle of the participant.

The study medication might reduce the effectiveness of oral hormonal contraception (oestrogen and progestogen). In this case, an additional barrier method is required (e.g., a condom) throughout the study and for at least 1 month after the last dose of study medication or placebo.

The study doctor will check that the method you are using is acceptable.

Any woman who finds that she has become pregnant while taking part in the study, should immediately tell the study doctor. The study doctor will ask to follow your pregnancy to its outcome. If a female partner of a male participant in the study becomes pregnant, she will be asked if the Sponsor can follow-up on her pregnancy. There will a separate Informed Consent Form for this. The study doctor will explain this to you.

What are the Possible Benefits of me Taking Part?

You may not receive any direct benefit from taking part in this study, but we hope the information gained from this study will benefit people living with PD in the future.

What Happens When the Research Study Stops?

If you complete the whole 18-month Treatment Period, and your study doctor agrees, you will have the option to take part in a different study called an Open Label Extension (OLE) study. All participants of the OLE study will receive the study medication and will have long-term access to the study medication. Placebo will not be used in the OLE study. If you wish to take part in the OLE study, you will be given a separate Participant Information Sheet and Informed Consent Form to read and sign. The study doctor will explain this in more detail.

The study doctor will discuss alternative treatment options with you if you do not wish to enter the OLE study or you are not eligible.

What if Relevant New Information Becomes Available?

You will be informed in a timely manner, if any relevant new information about this study medication or this study becomes available that may alter your willingness to continue to participate.

What Will Happen if I Don't Want to Carry on with the Study?

Your participation in the study is voluntary. If you agree to participate, you are still free to withdraw your consent at any time without giving a reason. You will not need to explain your reasons for leaving the study. If you leave the study this will not affect your future care. If you decide that you would like to leave the study, you should tell your study doctor.

Additionally, your participation in the study may be stopped for reasons such as:

- You do not follow the study doctor's instructions;
- You become pregnant (for female study participants only);
- Something serious happens to you which may require treatment;
- The study doctor decides it is in the best interest of your health and welfare to discontinue;
- There are not enough study participants in the study;
- The study is stopped by the regulatory authorities; or,
- The Sponsor stops or suspends the development of the study medication.

What About Research Related Injury?

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the study team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this using the contact details found in the "Further information and contact details" section.

Harm:

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, you may have grounds for legal action for compensation against the Sponsor, NHS Trust or Private Clinic. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). In accordance with the ABPI Guidelines, the Sponsor will pay compensation where the injury probably resulted from:

- A medication being tested or administered as part of the study protocol.
- Any test or procedure you received as part of the study.

Any payment would be without legal commitment. (Please ask if you wish more information on this).

In accordance with the ABPI Guidelines, the Sponsor will not be bound to pay compensation where:

- The injury resulted from a medication or procedure outside the study protocol.
- The protocol was not followed.

If you have private medical insurance, you are advised to inform your provider of your consideration to take part in a clinical research study as this may affect your cover. This is to make sure that you will not affect your medical insurance by being in a clinical study.

Will Information About Me be Kept Confidential?

UCB Biopharma SRL is the sponsor for this study based in Belgium. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Sponsor will keep identifiable information about you for at least 25 years after the end of the study.

We use personally-identifiable information to conduct research to improve health and care. As a pharmaceutical company, we have a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. This means that we will use your data, collected in the course of the study, in the ways needed to conduct and analyse the study.

You can ask to see the information that has been collected about you. If you think any of it is wrong, you can ask your study doctor in writing if it can be changed or removed. You can also ask that we can restrict the use of your personal information. However, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The study site will keep your name, NHS number, contact details and date of birth confidential and will not pass this information to Sponsor. The study site will use this information as needed, to contact you about the study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Sponsor and regulatory organisations may look at your medical and research records to check the accuracy of the study. Sponsor will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. The study site will keep coded identifiable information about you from this study for 25 years after the study has finished.

When you agree to take part in this study, the information about your health and care may also be used by Sponsor and provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by the Sponsor, organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research to the extent applicable and other applicable regulations. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

In order to perform the remote visits at your home, your personally identifiable information (PII) (including your name, address, date of birth, and phone number) will be shared with the Home Trial Support service provider, the Medical Research Network (MRN). The MRN will share your data with third party organisations (nursing agencies and couriers) for the purposes of arranging and performing remote visits at your home address. The PII will be kept secure and confidential and will be destroyed at the end of the study.

Within the European Economic Area, the data privacy laws and regulations have the same level of data protection as in your country. When data is transferred to countries that do not provide the same standard of legal protection for your personal data as in the European Economic Area, the Sponsor takes measures to ensure that your personal data is appropriately protected in accordance with the data privacy laws. These measures include Binding Corporate Rules available on the website of the Sponsor (www.ucb.com) for transfers within the Sponsor's group of companies, and contractual protections for transfers to certain other international recipients of your personal data (e.g. so called "Standard Contractual Clauses").

You can ask to see the information that has been collected about you. If you think any of it is wrong, you can ask your study doctor in writing if it can be changed or removed. You can also ask that we can restrict the use of your personal information. If you change your mind about taking part, we cannot remove the personal information that was collected for this research study before you stopped.

If you wish to raise a complaint on how we have handled your personal data, you can contact Sponsor's data protection officer who will investigate the matter. If you are not satisfied with our response or believe

we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Sponsor's data protection officer is Jean-Marie Schollaert and you can contact him by e-mail dataprivacy@ucb.com or by mail at UCB Biopharma SPRL, Allée de la Recherche 60, B-1070 Brussels, Belgium, if you wish to find out more about how we use your information. We suggest however that you first contact your study doctor or the data protection officer of the study site at compliance@re-cognitionhealth.com, because the Sponsor only holds coded information and cannot identify you directly.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

What will happen to any samples I give?

Biological samples may be collected, processed, and reported as necessary for purposes of the trial. Your biological samples will be handled in the following ways:

- Laboratory samples for routine laboratory, infection and virus, blood clotting, and pregnancy tests will be destroyed at the end of the study.
- Blood samples for study drug concentration measurements (PK blood samples) will be destroyed at the end of the study.
- Blood (including samples for genetic analysis) and CSF exploratory biomarker samples will be stored at a secure long term facility selected by UCB for a maximum of 20 years after the end of the study.

Access may be provided to the Sponsor, its business partners and collaborators, their group companies and their contract service providers (e.g., laboratories). Sample labels and analysis results will be kept confidential and not reveal your identity as described for other medical data above.

Stored samples might be used for future research to answer additional scientific questions related to the study medication/PD. The results of these research analyses may help UCB understand better how the body responds to the study medication or related medications, and understand the susceptibility, severity, and progression of PD. Researchers may also use your samples for biomarker discovery or development of new methods in view of the development of the study medication or other drugs. It is also possible that UCB may decide not to perform any additional analyses, for example in a situation where the clinical outcome of the main study would not justify it.

The results of the aforementioned analyses are for research purposes only and not for medical diagnosis or treatment decision making. They will not influence any medical diagnosis or treatment decisions for you.

Unless required by law, we will not provide you with test results or make any results available to you, any insurance company, your employer, your family, the study doctor, or any other doctor who treats you now or in the future. You may request the results of any research performed on your sample. It will not, however, be possible to interpret any results for you.

All biological samples will only be used for the purposes explained in this participant information sheet and informed consent form.

If you withdraw your consent, the biological samples that have been collected (but not analysed) before the withdrawal of your consent and the data obtained from it, can also still be used by the Sponsor.

You may however ask your study doctor for destruction of those samples. If this impacts the validity of the study, the destruction may be postponed till the end of the study.

The results of the future biomarker analyses or immune response analysis may support the development of new tests or diagnostic that may direct the choice of a medicine to the right patient. You may request the results of any research performed on your sample. It will not, however, be possible to interpret any

results for you. Finally, you also understand and agree that the individuals in UCB affiliates (or representatives working on their behalf) that may be given access to your coded health information may not always work under the direct supervision of a health professional. However, UCB ensures that these individuals will only have access to your information for technical reasons and will not take any decision regarding you or your participation in the trial, and will be subject to a confidentiality obligation. UCB will be the owner of the study results. If products or other valuable discoveries result from research using your samples and/or data, these products and discoveries may be used commercially by UCB and its collaborators, but will not generate income or property rights for you.

Involvement of the General Practitioner (GP)/Neurologist

Your study doctor will inform your GP and/or neurologist that you are taking part in this study and may ask them to provide relevant medical information about you if necessary.

Will Any Genetic Tests Be Done?

Yes. Cells in your body contain a type of material called DNA (deoxyribonucleic acid). DNA is what your genes are made of. Genes carry hereditary information. Genes are inherited from your parents and control growth, development, and how your body functions. For example, some genes control the colour of your hair or eyes. Scientists have learned a lot about how genes work. There are many differences in DNA from one person to another which may explain why an individual develops a particular disease or why a medication works better for one person than for another. We will collect blood samples from you from which DNA will be extracted, and tested for genetic variations.

The Sponsor will look at potential biomarkers (including genetic biomarkers). Your biomarker samples (including genetic biomarkers) will be collected at Visit 2, Visit 12 and Visit 15. The biomarkers samples will be analysed for DNA and ribonucleic acid (RNA) (which carry genetic information). DNA samples will also be used for research related to the study medication, PD and related diseases.

What Will Happen to the Results of this Research Study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

A description of this clinical trial will also be available through the public website *https://www.clinicaltrialsregister.eu*. This website will include information on the trial and summary of the results but will not include any information that can identify you. You can search this website at any time.

Who is Organising and Funding the Research?

UCB, the Sponsor, is organising and funding this clinical research study. The Sponsor of this study will pay the study site for including you in this study.

Who Has Reviewed the Study?

All research in the United Kingdom is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been given favourable opinion by the **East of Scotland Research Ethics Committee**.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA).

Further Information and Contact Details

If during this study, you have questions concerning the nature of the research, the study medication or your rights, or you believe that you have sustained a research-related injury, you should contact:

Study Doctor: Dr Emer MacSweeney
Phone Number: 020 3355 3536 (Option 1)

Study Coordinator: Hope Moonan
Phone Number: 020 3355 3536 (Option 1)

Address: Re:Cognition Health Ltd., 45 Queen Anne Street, London, W1G 9RU

If you need to report side effects or are feeling unwell, there is a 24 hour contact number:

Phone Number 07540 802222

If you have questions about your rights as a research participant, or do not feel comfortable speaking with your study doctor please ask the study site for details or contact:

Independent Advisor: Compliance team Phone Number: 020 3355 3536

Re:Cognition Health Brain and Mind Experts

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clinicaltrials@re-cognitionhealth.com
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+44(0)20 3355 3536 (tel.)
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Informed Consent Form

Title of Study	A double-blind, placebo-controlled, randomized, 18 month Phase 2a study to evaluate the efficacy, safety, tolerability and pharmacokinetics of oral UCB0599 in study participants with early Parkinson's disease
Short Title	A double-blind, placebo-controlled, randomized, Phase 2a study with oral UCB0599 in study participants with early Parkinson's disease
Protocol Number	PD0053
IRAS ID	1003518
Sponsor	UCB Biopharma SRL
Study Doctor	Dr Emer MacSweeney
Participant ID	

By signing and dating this document,		**Please initial each box**
1.	I confirm that I have had time to read carefully and understand the Participant Information Sheet and Informed Consent Form provided for this study.	Patient Initial
2.	I confirm that I have had the opportunity to discuss the study and ask questions, and I am satisfied with the answers and explanations that I have been provided.	Patient Initial
3.	I give permission for my medical records to be reviewed by the Sponsor or designee and/or representatives of any Regulatory Authorities.	Patient Initial
4.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. I understand that the Sponsor can continue to use the information about my health collected during the study to preserve the integrity of the study, even if I withdraw from the study.	Patient Initial
5.	I agree to the use of my personal data as described in this form. In particular, I agree that my coded personal data may be transferred worldwide, including outside the European Economic Area (EEA), even in countries that do not have data privacy laws equivalent to those in force in my country, and submitted to Regulatory Authorities where the study medication may be considered for marketing.	Patient Initial
6.	I agree to my PII (including my name, address, date of birth, and phone number) being shared with the Home Trial Support service provider, MRN. I agree that MRN can also share this data with third party organisations (nursing agencies and couriers) for the purposes of arranging and performing remote visits at my home address.	Patient Initial
7.	I also agree that my right to view and access, and to modify, correct, restrict and delete the collected information on my health may be postponed to ensure the quality of scientific results and to comply with legal or judicial retention periods.	Patient Initial
8.	I understand the use of my personal data as described in this participant information sheet and informed consent form.	Patient Initial
9.	I agree that my biomarker samples will be stored at a secure long-term facility for a maximum of 20 years. I understand it will be used for future research, which may	Patient Initial

help the Sponsor to better understand how PD develops, how the body deals with the disease and responds to the study medication or related medications.	
10. I agree that my genetic biological samples can be collected for relevant analysis.	Patient Initial
11. I agree to the retention of my samples for assay development.	Patient Initial
12. I agree that information about my health may be used by people who do not work under the direct supervision of a health professional.	Patient Initial
13. I agree to my GP and/or neurologist being informed of my participation in this study and providing relevant medical history/data about me to the study doctor if necessary.	Patient Initial
14. I understand that if I have a positive result for hepatitis, I will not be able to participate in this study, and the result will be reported to health authorities as per local requirements.	Patient Initial
15. I understand that if I agree to an optional COVID-19 test and I have a positive result that this result will be reported to health authorities as per local requirements.	Patient Initial
16. I understand that I will receive a copy of this Participant Information Sheet and Informed Consent Form and signed Informed Consent Form.	Patient Initial
17. I agree to take part in this study.	Patient Initial
For participants who are able to become pregnant only: 18. I understand that if I find out that I have become pregnant while taking part in the study I should immediately tell the study doctor. I also understand that the study doctor will ask to follow my pregnancy to its outcome.	Patient Initial

Optional Consent:

Please initial the appropriate box:

☐ I **agree** to undergo lumbar puncture for CSF sampling. CSF sampling is (only) optional at End of Treatment Visit/Visit 15. At Visit 2, and Visit 12, CSF sampling is mandatory if you agree to this optional procedure

OR

☐ I **do not agree** to undergo lumbar puncture for CSF sampling.

Please initial the appropriate box:

☐ I **agree** to have pictures taken and/or provide pictures of my skin reactions and/or swelling in case I experience a possible allergy-like reaction.

OR

☐ I **do not agree** to have pictures taken and/or provide pictures of my skin reactions and/or swelling in case I experience a possible allergy-like reaction.

Please initial the appropriate box:

☐ I **agree** to wear the Study Watch in compliance with the procedure schedule.

OR

☐ I **do not agree** to wear the Study Watch in compliance with the procedure schedule.

Please initial the appropriate box:

☐ I **agree** that my coded data collected in this study, including Study Watch data if collected, may be further used by UCB and external researchers to answer additional scientific questions related to the study medication and/or PD. I also agree that the data collected by the Study Watch may be used to allow researchers to answer questions about the relationship of signals from the Study Watch to motor and non-motor symptoms of PD, and to develop better measurements of daily function.

OR

☐ I **do not agree** that my coded data collected in this study, including Study Watch data if collected, may be further used by UCB and external researchers to answer additional scientific questions related to the study medication and/or PD. I also agree that the data collected by the Study Watch may be used to allow researchers to answer questions about the relationship of signals from the Study Watch to motor and non-motor symptoms of PD, and to develop better measurements of daily function.

STUDY PARTICIPANT			
	First name / last name (capital letters)	Signature	Date
AUTHORIZED PERSON OBTAINING CONSENT (Medically qualified* and appropriately qualified under national law for device, if applicable)			
	First name / last name (capital letters)	Signature	Date
WITNESS (Where required)			
	First name / last name (capital letters)	Signature	Date

*If the study doctor delegates the responsibility of signing the informed consent to any of their staff working on a UCB study, then UCB require the delegated person to be medically qualified (e.g., a qualified Health Care Professional as specified by local regulations). However, if local regulations state non-medically qualified staff working on a study can sign the informed consent, then that is acceptable as long as they adhere to the local regulations.

When completed, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.