Re:Cognition Health Brain and Mind Experts

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Participant Information Sheet and Informed Consent Form for Participants Ages 16 to 17Years Old

Dr Christina Georgoula

Re:Cognition Health, 45 Queen Anne Street, London, W1G 9JF
0203 355 35 36

London – Brent Research Ethics Committee

Study Title: Phase 3, multicenter, randomized, double-blind, group sequential, placebo-controlled study to assess efficacy and safety of rimegepant for the treatment of migraine (with or without aura) in children and adolescents ≥ 6 to <18 years of age.

Study Short Title: Phase 3 Randomized study in children and adolescents with migraine

Protocol Number: BHV3000-311

IRAS ID: 297615

Sponsor: Biohaven Pharmaceuticals,

Name of Doctor Administering Consent:

24-hour contact number(s): 07776 055 701

Important

This informed consent ("permission") form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that is not clear to you.

Joining a study is an important decision. You should ask the study team any questions you may have about the study and this informed consent form before making a decision to participate.

Also, you may have your GP (General Practitioner) call the study doctor to ask any questions he/she feels are necessary to evaluate the study and your possible participation in it.

You may take home an unsigned copy of this informed consent form to think about it or discuss it with family or friends before making the decision to consent to your participation in the study.

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Why is this study being done?

This study is a kind of experiment called a clinical research study. Clinical research helps doctorsunderstand how a study medicine works before it is given to lots of people. The medicine ("studydrug") in this research is called rimegepant. You are being asked to be in this study because you have migraines. If you do not want to take part in the study, you don't have to.

Rimegepant is a medicine that is given to adults with migraine in the United States. For this study,researchers want to see if rimegepant works and is safe for treating migraine in participants in agegroup 16 to 17).

If you do not want to be in this study, you do not have to be in it. If you decide you want to be in it and then change your mind later, that is fine. No one will be upset or angry with you. If you choose to be in the study, you can ask questions at any time. This study involves research, which means the purpose of the study is to collect information about a medical treatment. You still needto see your regular doctors and migraine doctor, even if you are in this study.

The main purpose of this study is to learn how well the study drug works and how safe the study drug is to treat migraine in children and adolescents compared with placebo. A placebo looks likethe study drug but does not contain any active drug. It is not designed to treat any disease or illness.It is designed to be compared with the study drug to learn if the study drug has any real effect.

No one can force you to be in this study. If you decide to say no, your doctors will not be angry and will continue to take care of you, just like normal. If you decide to stop the study once you have started, that is okay too.

How many people will take part in this study?

This study will take place in approximately 190 centres in the United States, Canada, and Europewith about 2100 eligible participants with migraine. Approximately 1746 adolescents (between the ages of 16 and 17 years) and 354 children (between the ages of 6 and 15 years) are expected to take part.

How long will my participation in this study last?

It is planned that you will be in this study for up to 19 weeks and you will need to come to the study centre up to 4 times over this period.

What will happen during this study?

The study is divided into 3 time periods: a screening period, a treatment period, and a follow-up period. During each study period, you will have at least 1 visit with your study doctor at

the centre.Study visits will generally last between 1 to 2 hours.

Before any study-related tests and procedures can be done, you will be asked to read and sign this informed consent form. After you sign this informed consent form, the study will begin with a screening visit. The purpose of the screening visit is to determine whether it is ok for you to be in the study. The study doctor will explain if they find it is not a good idea for you to be in the studyand will discuss other treatment options with you then.

If the study doctor determines that it is ok for you to be in the study, you will be randomly assigned(like the flip of a coin) to receive one of the following treatments:

- Rimegepant (study drug)
- Placebo (Inactive drug)

The chance of receiving rimegepant or placebo (Inactive drug) will vary during the study. At somepoint, participants will have a 50% (1 in 2) chance of receiving rimegepant and a 50% (1 in 2) chance of receiving placebo (Inactive drug), and at some point, all participants will receive placebo(Inactive drug). You will not be told which treatment you are receiving.

There will be a time in which the study doctor and any other people involved in the study will know whether you are receiving rimegepant or placebo (Inactive drug) and another time where they will not. However, the study doctor will be able to find out what you are receiving, if it becomes necessary for them to know for your safety.

In this study, you could treat up to 2 migraine episodes of moderate or severe pain with the studydrug. The study doctor or study staff will give you instructions on how to take the study drug.

After the first dose of the study drug, the study doctor will evaluate you and determine how your study treatment will continue.

Study Procedures and Assessments
The procedures and assessments that will occur are described below.

Screening Visit (in clinic visit 1)

After reading and signing this consent document, the following screening tests and procedures willthen be done:

- Your past and current medical history will be reviewed, including your migraine history.
- You will be asked to answer questions about your demographic information (for example,date of birth, age, sex at birth, ethnicity, and race).
- You will be asked about all of the prescription and over-the-counter medications and supplements that you are taking or have previously taken.
- You will have a complete physical exam including a puberty assessment.

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- Your height, weight, and vital signs (body temperature, breathing rate, blood pressure, andheart rate) will be measured.
- You will have an electrocardiogram (ECG). An ECG is a test that measures the electrical activity of the heart. A technician will place patches on your chest that will be connected by wires to a machine. The machine will record the electrical activity of your heart.
- You will have blood samples taken to make sure it is safe for you to take part in this study
  . If possible, you should arrive for these blood tests after fasting (restricting food and drink).

    - A blood pregnancy test will be done if you are able to become pregnant. The resultof the pregnancy test must show that you are not pregnant for you to take part in this study.

- You will have a urine (pee) sample collected for the following:

  - To make sure that you can safely take part in the study
    - To screen for drug use

- You will be asked questions about whether you are having any thoughts or behavioursabout hurting yourself.
- You will be asked to complete a questionnaire about how migraines affect your schoolattendance and your ability to perform certain activities.
- You will be asked about how you are feeling.
- You will receive a paper diary called the “Concomitant Medication Use Log” to recordthe use of any other medications that you take.

Baseline Visit (in clinic visit 2)

You will be scheduled to return to the study centre approximately 3-28 days after the screeningvisit for a baseline visit. The following tests and procedures will be performed:

- Any changes in your health since your last visit will be reviewed.
- A review of the prescription and over-the-counter medications and supplements you arecurrently taking or has previously taken will be done.
- You will be asked how you are feeling.
- Your vital signs and weight will be measured.
- If you are able to become pregnant, a urine (pee) sample will be collected for a pregnancytest. The result of the pregnancy test must show that you are not pregnant to continue to participate in this study.
- You will be asked questions about whether you are having any thoughts or behaviours about hurting yourself.

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- The study doctor and study staff will give you study drug and will tell you how and whento take the study drug.
- You will be provided with a handheld device called an eDiary (This device is similar to a cell phone except you can only use it to answer questions about your migraines. All of theanswers are saved and sent to your study doctor from this device). You need to record your migraine pain intensity and whether you have other symptoms such as nausea, sensitivity or aversion to noise (phonophobia) and/or sensitivity or aversion to light (photophobia). You will be trained on how to use the eDiary by the study staff. The use of the eDiary is required for you to be part of this study.
- You will continue to update the "Concomitant Medication Use Log" to record the use of any other medications you take.
- You will receive a paper diary called the "Rescue Medication Use Log" to record the use of any "rescue" medications used to treat your migraine.
- You will receive a paper diary called the "2 Hour Post Dose Diary" to record if you were asleep 2 hours after taking study drug.

Study Treatment Period (up to 15 weeks)

During the study treatment period when you have a migraine that is moderate to severe intensity, you must answer the questions in your handheld device before taking study drug.

- You will need to record your migraine pain intensity at the onset of your migraine in youreDiary. You will also record whether or not you have nausea, photophobia, or phonophobia.
- If you are able to become pregnant and think that you may have become pregnant, you should not take the study drug and you should contact the study doctor as soon as possible.
- After completing the eDiary assessments, you will take the study drug by putting it on or under your tongue and allowing it to dissolve.
- At 30 minutes and 1, 1.5, 2, 24 and 48 hours after taking the study drug, you will record your migraine symptoms in your eDiary. You will record whether or not you have nausea,photophobia, or phonophobia at the same time points. You will also be asked to rate your level of disability in your eDiary.
    - If you do not feel better 2 hours after taking the study drug and after the 2 hour assessments have been completed on the eDiary, you can take other permitted "rescue" medications (for example, ibuprofen, acetaminophen up to 1000 mg/day or any other type of nonsteroidal anti-inflammatory drugs (NSAIDs are medicinesthat are widely used to relieve pain, reduce inflammation, and bring down a high

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- temperature)], triptans, antiemetics [for example, metoclopramide or promethazine] or baclofen). All "rescue" medications used should be recorded in the provided paper diary called the "Rescue Medication Use Log".
- If needed, after 48 hours after study drug, you can take your prescribed standard of care medication to treat your migraine. Standard of care medication should be recorded on the "Concomitant Medication Use Log".

- You will complete the paper diary called the "2 Hour Post Dose Diary" to record if you were asleep 2 hours after taking study drug.
- If you do not have a migraine within 45 days from baseline for the treatment of the first migraine attack or within 45 days from visit 3 for the 2nd migraine attack, you should not take the study drug. You will be scheduled to return to the study site for an end of treatment visit with your unused study drug, eDiary, and paper diaries.

Post-Treatment/End of Treatment Visit (in clinic visits 3 and visit 4):

Within 7 days of taking study drug for the first and the second migraine attack, you will be askedto return to the study centre for a visit.

The following tests and procedures will be done at both visits:

- You will be asked how you are feeling.
- Your vital signs and weight will be measured.
- You will be asked questions about whether you are having any thoughts or behaviours about hurting yourself.
- You will also be asked about any medications that you have taken since your last study visit.
- Your eDiary will be reviewed and returned.
- You will return your medication paper diaries called the "Rescue Medication Use Log" and the "Concomitant Medication Use Log".
- You will return your 2 hour paper diary called the "2 Hour Post Dose Diary".
- You will return the unused study drug or packaging of the used study drug.

The following tests and procedures will be done at **visit 3 only**:

- A pregnancy test will be done if you are able to become pregnant (urine sample)
- Based on the study doctor's assessment, they will determine if you will continue for a second treatment with study drug. If so, they will give you

study drug and will tell you howand when to take the study drug.

The following tests and procedures will be done at the **end of treatment visit only**:

- You will have a physical examination
- You will have blood samples collected for standard laboratory safety tests. If possible youshould arrive for these blood tests after fasting.
    - A blood pregnancy test will be done if you are able to become pregnant
- You will have a urine sample collected for safety and screening for drug use
- You will return the eDiary handheld device.

Unscheduled Visit

You may have unscheduled study visits with your study doctor for your safety.

Note: Due to the COVID-19 pandemic, there may be alternatives to visiting the study centre for certain assessments. This includes having virtual visits via phone or video conferencing or havingblood and/or urine tests done at local laboratories or by an in-home vendor. Screening, Baseline and Post-Treatment (visit 3) visits must be done at the study centre.

What are the benefits of being in this study?

There is no guarantee that you will receive any benefits. You will be helping others by volunteeringfor the study. You may feel that you are benefiting in the following ways:

- Taking part in the study will be at no cost to you. Your condition will be checked as long as your participation in the study lasts. However, services provided and evaluations carriedout as part of the study should not be seen as a substitute for a careful evaluation, ongoing medical care, or follow-up by your GP.
- The study drug may help to relieve your symptoms.
- You and your family may learn more about your migraines.

What are the risks of being treated with rimegepant?

Studies in humans

Rimegepant is currently approved by the US-FDA (US-Food and Drug Administration) to preventand treat migraine attacks in adults. By the end of August 2021, approximately 5661 people havereceived rimegepant at any dose while participating in migraine or trigeminal neuralgia studies.

Temporary elevations (increase) of liver enzymes (an indication of possible liver injury) and

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muscle enzymes (an indication of possible muscle injury) have been infrequently reported in studies with rimegepant. However, a causal relationship between rimegepant and these laboratoryfindings has not been found at approved doses. Upper respiratory tract infection, cold-likesymptoms, nasal sinus swelling, urinary tract infection, flu, back pain, bronchitis, nausea, abdominal pain/indigestion, dizziness, joint pain , diarrhoea, constipation, and headache were alsoinfrequently reported.

Allergic reaction risks:
With any medication, there is a small but real risk of allergic reactions that can be life-threateningor fatal. Severe reactions have included difficulty breathing and rash, and can occur days after taking the medication.

Some symptoms of allergic reactions are:

- Skin itching, redness, rash
- Difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

If you have an allergic reaction, you must get emergency medical care immediately.

Other less common side effects in humans have been reported. The doctor or staff can discussthese with you. Any side effect, rare or not, may worsen and be life-threatening.

What are the possible risks of study procedures?
You may feel discomfort during some of the tests and there are some risks, such as:

- Blood samples: Possible side effects from blood drawing include faintness, inflammationof the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from theelectrodes (small sticky patches) that are used.

  Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with. If you decide not to complete certain questionnaires, you may not be eligible to continue participation in this study. If you are having suicidal thoughts, call the study doctor at the telephone number listed on the first page of this form.
- If you're feeling overwhelmed, or like you want to hurt yourself, you can call HopelineUK (0800068414) or text 85258 for Young Mind's Crisis Messenger service and a counsellor will talk things through with you confidentially. If you feel like you may attempt suicide, or you have seriously hurt yourself, it's an emergency. You or a trusted adult should call 999 and ask for an ambulance.
- If you receive placebo (the inactive drug) as part of this study, your

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symptoms of may notimprove.

- Your study doctor may discuss sensitive topics such as mental wellbeing and suicideprevention and you can choose not to take part if you are not comfortable with it.

What are the unforeseen risks?

Since rimegepant is investigational in the paediatric population, there may be other risks that are unknown when it is taken alone or in combination with other medications. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

It is possible that new, unanticipated, different, or worse symptoms will result from rimegepant. Ifthere are significant new findings during this course of your participation in this research study orother ongoing research your doctor will provide you with the relevant information.

Additionally, there may be unknown risks to a pregnancy, embryo, or foetus if you or your femalepartner become pregnant.

Pregnancy/Contraception

Females

Taking the study drug may involve unknown risks to a pregnant woman, an embryo, a foetus (unborn baby), or a breastfeeding infant. Therefore, if you are pregnant, planning to become pregnant, or breastfeeding a child, you cannot take part in this study.

Before entering the study, a serum (blood) pregnancy test will be done for all girls who are able tobecome pregnant (i.e. girls who have had their first menstrual period). This test might not detect an early pregnancy. Urine pregnancy tests will be repeated during the study and a serum pregnancytest will be done at the end of treatment visit.

The only certain way not to become pregnant is to not have sex. If you choose to have sex duringthe study, you must use acceptable methods of contraception while you are taking part in this studyand for 60 days after your last dose of study drug. If you are already using a method of contraception, the study doctor or study staff will discuss with you if your current method of contraception is acceptable for use during this study.

Methods of acceptable contraception include:

- abstinence (not having sex)
- the combination of a male condom and hormonal contraception to prevent ovulation (oestrogen and progestogen or progestogen-only) or an intra-uterine contraception device (IUD) (with or a without hormone release

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system) used since at least 4 weeks prior to studydrug administration
- the simultaneous use of a male condom and, for the female partner, a diaphragm or cervicalcap with intravaginal applied spermicide.

You should not take the study drug if you are pregnant. If during the study you become pregnant,you should tell the study doctor immediately, and you will be withdrawn from the study. You willbe asked to complete the final procedures and assessments to terminate the study.

Males

If you choose to have sex during the study, you and your female partner should be compliant withacceptable methods of contraception that may include:

- abstinence (not having sex)
- the combination of a male condom and for the female partner, use of hormonal contraception to prevent ovulation (oestrogen and progestogen or progestogen-only) or anIUD (with or a without hormone release system) used since at least 4 weeks prior to studydrug administration
- the simultaneous use of a male condom and, for the female partner, a diaphragm or cervicalcap with intravaginal applied spermicide.

If your partner becomes pregnant, the Sponsor may want to receive updates on the progress of thepregnancy and its outcome. If you agree to this, your pregnant partner will be asked to sign a separate informed consent.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London – Brent Research Ethics Committee.

What if there are new findings?

If new findings that would affect your safety and willingness to participate in the study are identified while you are in the study, you will be told as soon as possible so you can decide whetherto leave the study or continue. If you continue, you will be required to sign a new informed consentform.

What other options are available if I do not take part in this study?

You do not have to take part in the study to treat your migraine. There are treatments available formigraine, including prescription and non-prescription medications, as well as drugs approved by the MHRA (Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the United Kingdom

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which is responsible for ensuring that medicines and medical devices work and are acceptably safe.)) specifically for the treatment of migraine. The study doctor will discuss the risks and benefits of these treatmentswith you. Please talk to the study doctor about your options before you decide whether or not youwill take part in this study.

Your GP or the study doctor can answer any questions that you have about other treatments.

You should also contact your GP to ask about other research currently being done in the treatmentof migraine.

Who is paying for this study?

This study is being funded by Biohaven. The study doctor will be paid for his/her work in this study.

What are the costs?

The study drug will be given at no cost to you or your child, and you or your child will not be charged for any study doctor visits, laboratory work, tests, or procedures that are needed for the study.

Will I be paid to take part in the study?

You will not be paid to take part in the study. The Sponsor will cover the costs of the study drugsand all research-related tests and clinic visits required for this study. The research may lead to newtests, drugs, or other products for sale. If it does, you will not get any payment or share in any profits. If applicable, you may be reimbursed for reasonable expenses incurred due to your participation in the study (for example, taxi fare or parking fee). Please discuss this in details withyour study doctor or any member of the study team

What if I gets sick or hurt?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions on telephone 0203 355 35 36

The sponsor 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).They will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol
- Any test or procedure you received as part of the trial

You will not lose any of your legal rights or release Biohaven, the study doctor, the study staff, orstudy site from liability for mistakes by signing this consent document.

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What are the benefits of being in this study?

There is a chance that the study drug used in the study may help your condition. At this time it isnot possible to know for certain all the benefits.

Insurance

If you have private insurance such as life insurance, travel insurance, private medical insurance, you should check with the insurance company before agreeing to take part in this study to ensureyour participation will not affect any coverage you have.

Can I leave the study after it has begun?

Yes. Taking part in this study is voluntary, and you can leave the study at any time for any reason.There will also not be any penalty or loss of benefits to which you are entitled at this site if you decides not to take part or if you decides to leave the study.

If you decides to leave the study, you should contact the study doctor, who will explain the safestway to stop being in the study, which may involve completing some final tests and examinations.You should also contact your GP so he or she can provide you with the best course of continuing care.

The study doctor or Biohaven can remove you from the study, without your permission, for any reason. Possible reasons for doing so include the following:

- any change in your medical condition that might make continuing in the study harmful tohim/her
- you do not follow the study doctor's instructions
- finding out that you does not meet the study requirements
- you becomes pregnant
- the study is cancelled
- administrative purposes

What will happen to the samples that I will provides?

The blood and urine samples that you gives will be used only for specific tests that are neededfor this study. Your samples will be processed by a central laboratory (Q2 Solutions). Sampleswill be tested and destroyed according to the standard procedures of the laboratory.

What happens when this study stops?

When the study stops, you will be under the care of your GP, who will decide the best way to treat your migraine. The study drug will no longer be available to you. You may be eligible to participate in a long-term safety study of rimegepant. You should talk to

the study doctor aboutthis possibility.

Will my records be kept private?

To participate in this study, you must read and sign the Privacy Notice Section at the end of this form (see Appendix 1).

Study information and results

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This websitewill not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. The trial will be registered in the EuropeanClinical Trial Registry https://www.clinicaltrialsregister.eu/ctr-search.

Who can I talk to about this study?

You can ask questions about the study any time. If you have a concern about any aspect of this study, you can call the study doctor any time. If you want to ask questions about what it means tobe in a research study you can call the following contact point.

Study Doctor/Contact Name: Dr Christina Georgoula

Daytime Telephone Number(s): 0203 355 35 36

24-hour Contact Number(s): 0777 605 5701

If you have questions about your rights as a research participant or if you have questions, concerns,or complaints about the research, you may contact:

Re:Cognition Health Compliance Team on 0203 355 35 36 or compliance@re-cognitionhealth.com

Re:Cognition Health Brain and Mind Experts

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Participant Information Sheet and Informed Consent Form for Participants Ages 16 to 17Years Old

Study Title:	Phase 3, multicenter, randomized, double-blind, group sequential,placebo-controlled study to assess efficacy and safety of rimegepant for the treatment of migraine (with or without aura) in children and adolescents ≥ 6 to <18 years of age
Short Study Title:	Phase 3 Randomized study in children and adolescents with migraine
Protocol Number:	BHV3000-311
IRAS ID:	297615
Sponsor:	Biohaven Pharmaceuticals,
Study Doctor Name and Address:	Dr Christina Georgoula 45 Queen Anne Street, London, W1G 9JF
Telephone number (s) **Daytime:** **After hours:**	 0203 355 35 36 0777 605 5701
Participant number:	

	Please initial each box
I confirm that I have read the information sheet dated 10 Dec 2021 (version 5.1.0) for the above study and agree to come to the study centre for visits.	
I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.	
I understand the risks of taking part in this study as described in this informed consent form.	
I understand that there is no guarantee that I will receive any benefits from taking part in this study.	
I freely consent to be treated with rimegepant or placebo under the study doctor's care.	
I confirm that all information that I have given about my medical history is correct to the best of my knowledge.	
I agree to my GP being informed of his/her participation in the study.	
I agree to ask questions about my health, take blood and urine samples and any examinations by the study doctor.	

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I agree to take the study drug one or two times at home when I experience a moderate to severe migraine and record my symptoms in an eDiary. I will also record the study drug and other medications timings in a paper diary.	
I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner and my future care can be discussed.	
I agree to collect my personal data including sensitive personal data, can be collected, used, and archived for purposes of carrying out the study and can be transferred to other countries for processing, including countries that may not have the same level of data protection as in my country of residence, as described in this Privacy Notice	
I understand that I will be told of any new information that might relate to my willingness to continue in the study.	
I will tell the study doctor if I have any physical or psychiatric ("mental health") symptoms or problems.	
I understand that I will receive a signed and dated copy of this informed consent form for my records.	

_____

Name of participant (print)

_____ _____

Signature of participant Date (dd/Mmm/yyyy)

_____

Name of study doctor or person administering consent (print)

_____ _____

Signature of study doctor or person administering consent Date (dd/Mmm/yyyy)

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FOR PARTICIPANTS WHO CANNOT READ

The participant has indicated that he/she is unable to read. This information sheet and consent document has been read to the participant by a member of the study team, discussed with the participant by a member of the study team, and the participant has been given an opportunity to ask questions to the study team.

_____
*Witness' Full Printed Name for Consent

_____ _____
Date Witness' Signature for Consent (Delete if not applicable)

*Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the consent and any other written information supplied to the participant. ICH Guidance for Industry E6 Good ClinicalPractice: Consolidated Guidance

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Appendix 1 - Privacy Notice

How will we use information about you?

We will need to use information from you, from your medical records and your GP for this researchproject.

This information will include your initials, NHS number and name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details.Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to outside the UK. They must follow our rules about keepingyour information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting informationabout your health from central NHS records, your hospital, your GP. If you do not want this tohappen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team.
- by sending an email to our Data Protection Officer, John Markow(john.markow@biohavenpharma.com)
- by ringing us on +001 203-404-0410.