< To be printed on site letterhead>

Parental/Legal Representative Informed Consent Form

[Investigator name]

[Investigator address or affiliation]

[Investigator telephone number]

[IRB/IEC name]

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: [Name of doctor]

24-hour contact number(s): [Site Emergency Phone Number]

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 for your child to participate.

Also, you may have your child's GP (General Practitioner) call the study doctor to ask any questions he/she feels are necessary to evaluate the study and your child's 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 your decision for your child to take part in the study

Why is this study being done?

Biohaven Pharmaceuticals, (Biohaven) is studying a drug called rimegepant as a possible treatment for migraine in children and adolescents (in age group 16-17) . This drug has been approved by the United States (US) Food and Drug Administration (FDA) for treatment of migraine in adults but is considered investigational in this study because it has not been approved for use in children and adolescents for migraine. For this study, researchers would like to see whether rimegepant is effective and safe for treating migraine in children and adolescents between the ages of 6 and 17 years. Your child is being asked to volunteer for this study because he/she has been diagnosed with migraine (with or without aura). If you do not want your child to take part in the study, your decision will be respected.

This is a research study. Volunteering for a research study is not the same as getting regular medical care. The purpose of a research study is to collect information about a medical treatment; the purpose of regular medical care is to improve your child's health. Being in this study does not replace your child's regular medical care, but your child may have additional evaluations or changes in his/her treatments during the study.

Your child does not have to be in this study. If your child decides not to take part in this study, your child can continue with his/her current medical care.

Rimegepant is a type of drug called a calcitonin gene-related peptide receptor antagonist. It is thought to relieve migraine symptoms by blocking or reversing the widening of blood vessels, inflammation, and pain signals in the brain that are caused by migraine.

The main purpose of this study is to learn how well the study drug works and how safe the study drug is in children and young people compared with placebo. A placebo looks like the 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.

The study has been reviewed and approved by the Ethics Committee [insert name as applicable] and an authorization from the applicable competent authorities Medicines and Healthcare Products Regulatory Agency according to the legislation in force.

How many people will take part in this study?

This study will take place in approximately 190 centres in the United States, Canada, Europe with 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 child's participation in this study last?

It is planned that your child will be in this study for up to 19 weeks and your child 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, your child 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 and your child will be asked to read and sign a participant information sheet and assent form. After you and your child sign these informed consent/assent forms, the study will begin with a screening visit (described in detail below). The purpose of the screening visit is to determine whether your child meets the requirements to take part in this study. If your child does not meet the requirements, the study doctor will explain why and will discuss with you and your child other treatment options.

If the study doctor determines that your child meets all of the requirements to be in the study, your child 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 will vary during the study. At some point, participants will have a 50% (1 in 2) chance of receiving rimegepant and a 50% (1 in 2) chance of receiving placebo, and at some point, all participants will receive placebo. You and your child will not be told which treatment he/she is receiving.

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

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

After the first dose of the study drug, the study doctor will evaluate your child and determine how the 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 will be done:

- Your child's past and current medical history will be reviewed, including his/her migraine history.

- You and your child will be asked to answer questions about their demographic information (for example, date of birth, age, sex at birth, ethnicity, and race).
- You and your child will be asked about all of the prescription and over-the-counter medications and supplements that he/she is taking or has previously taken.
- Your child will have a complete physical exam including a puberty assessment (if applicable).
- Your child's height, weight, and vital signs (body temperature, breathing rate, blood pressure, and heart rate) will be measured.
- Your child 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 child's chest that will be connected by wires to a machine. The machine will record the electrical activity of your child's heart.
- Your child will have blood samples taken for laboratory safety tests (to ensure it is safe for him/her to participate in the study) . If possible, your child should arrive for these blood tests after fasting.
    - A blood pregnancy test will be done if your child is able to become pregnant. The result of the pregnancy test must show that your child is not pregnant for her to qualify to participate in this study.
- Your child will have a urine sample collected for the following:
    - To make sure that he/she can safely take part in the study
    - To screen for drug use
- Your child will be asked questions about whether he/she is having any suicidal thoughts or behaviours using a scale called the Columbia-Suicide Severity Rating Scale (C-SSRS)
- Your child will be asked to complete a questionnaire about how migraines affect his/her school attendance and his/her ability to perform certain activities using a scale called the Paediatric Migraine Disability Assessment Score (PedMIDAS).
- Your child will be asked about how he/she is feeling.
- Your child will receive a paper diary called the "Concomitant Medication Use Log" to record the use of any other medications that they take.

Baseline Visit (in clinic visit 2)

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

- Any changes in your child's health since his/her last visit will be reviewed.
- A review of the prescription and over-the-counter medications and supplements your child is currently taking or has previously taken will be done.

- Your child will be asked how he/she is feeling.
- Your child's vital signs and weight will be measured.

- If your child is able to become pregnant, a urine sample will be collected for a pregnancy test. The result of the pregnancy test must show that she is not pregnant for her to continue to participate in this study.
- Your child will be asked questions about whether he/she is having any suicidal thoughts or behaviours (Columbia-Suicide Severity Rating Scale [C-SSRS]).
- The study doctor and study staff will give you and your child study drug and will tell you and your child how and when to take the study drug.
- You and your child 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 child migraines. All of the answers are saved and sent to your child study doctor from this device). You or your Child need to record his/her migraine pain intensity and whether they have other symptoms such as nausea, sensitivity or aversion to noise (phonophobia) and/or sensitivity or aversion to light (photophobia). You and your child will be trained on how to use the eDiary by the study staff. The use of the eDiary is required for him/her to be part of this study. You can help your child to use the e-Diary and if necessary, you can log into the e-Diary using your own PIN (personal identification number) and answer the questions on your child behalf.
- Your child's data will be securely, accurately and dependably transmitted from the handheld device to the study servers. All transmissions will be encrypted to help protect the confidentiality of your data.
- Your child will continue to update the "Concomitant Medication Use Log" to record the use of any other medications that they take.
- Your child will receive a paper diary called the "Rescue Medication Use Log" to record the use of any "rescue" medications used to treat their migraine.
- Your child will receive a paper diary called the "2 Hour Post Dose Diary" to record if your child was asleep 2 hours after taking study drug.

Study Treatment Period (up to 15 weeks)

During the study treatment period when your child experiences a migraine that is moderate to severe intensity, your child must answer the questions in his/her handheld device before taking study drug.

- Your child will need to record their migraine pain intensity at the onset of the migraine in their eDiary. They will also record whether or not they have nausea, phonophobia, or photophobia.
- If your child is able to become pregnant, and suspects that she may have become pregnant, she should not take the study drug and you or your child should contact the study doctor as soon as possible.
- After completing the eDiary assessments, your child will take study drug by putting it on or under their tongue and allowing it to dissolve.
- At 30 minutes and 1, 1.5, 2, 24 and 48 hours after taking the study drug, you or your child will record their migraine symptoms in their eDiary. They will record whether or not they

have nausea, phonophobia, or photophobia at the same time points. If your child is an adolescent (aged 12 to 17 years), they will also be asked to rate their level of disability in their eDiary.

- If your child does not feel better 2 hours after taking the study drug and after the two hour assessments have been completed on the eDiary, he/she 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 medicines that are widely used to relieve pain, reduce inflammation, and bring down a high temperature)), triptans, antiemetic's [for example, metoclopramide or promethazine] or baclofen). Non-permitted rescue medications include opioids, ergotamines, butalbital compounds, and muscle relaxants (except baclofen). All "rescue" medications used should be recorded in the provided paper diary called the "Rescue Medication Use Log".
- If needed, 48 hours after study drug, your child can take his or her prescribed standard of care medication to treat their migraine. Standard of care medication should be recorded on the "Concomitant Medication Use Log"

- You/your child will complete the paper diary called the "2 Hour Post Dose Diary" to record if your child was asleep 2 hours after taking study drug.
- If your child does 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, your child should not take the study drug. Your child will be scheduled to return to the study site for an end of treatment visit with your child's unused study drug, eDiary, and paper diaries.

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

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

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

- Your child will be asked how he/she is feeling.
- Your child's vital signs and weight will be measured.
- Your child will be asked questions about whether he/she is having any suicidal thoughts or behaviours (Columbia-Suicide Severity Rating Scale [C-SSRS]).
- Your child will also be asked about any medications that he/she has taken since his/her last study visit.
- Your child's eDiary will be reviewed and returned.
- You/your child will return his/her medication paper diaries called the "Rescue Medication Use Log" and the "Concomitant Medication Use Log".
- You/your child will return his/her 2 hour paper diary called the "2 Hour Post Dose Diary".
- You/your child will return the unused study drug or the 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 your child is able to become pregnant (urine sample)
- Based on the study doctor's assessment of your child, they will determine if your child will continue for a second treatment with study drug. If so, they will give you and your child study drug and will tell you and your child how and when to take the study drug.

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

- Your child will have a physical examination
- Your child will have blood samples collected for standard laboratory safety tests (approximately 5.5 mL or 1 teaspoon). If possible your child should arrive for these blood tests after fasting.
    - A blood pregnancy test will be done if your child is able to become pregnant
- Your child will have a urine sample collected for safety and screening for drug use
- You/your child will return the eDiary handheld device.

Unscheduled Visit

Your child may have unscheduled study visits with his/her study doctor for his/her 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 having blood 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 do my child and I have to do?

During the study, you will have the following responsibilities:

- Tell your child's study doctor if your child has any allergies, including drug allergies. If you are unsure, ask your child's primary doctor.
- Attend all scheduled visits.
- Use the eDiary to record details about your child's migraine as instructed by the study personnel.
- Take the study drug as directed.
- Return any unused study drug and containers as instructed by the study staff.
- Return the eDiary.
- Follow the study doctor's instructions about whether your child may continue to take his/her regular prescribed medications or over-the-counter medicines during the study period.
- Tell the study doctor of any changes to your child's current medications, illnesses or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- Tell the study doctor if your child plans to have an elective surgery or any other medical treatment or procedure.
- After taking the study drug, your child should take it easy to see how his/her body responds.

- Your child should continue to make regular visits to his/her primary doctor or any other special doctors your child was seeing before starting the study because being in the study does not replace regular medical care.
- Make sure that the study drug is kept out of the reach of children and people who have a limited capacity to read or understand. Your child is the only person who should take the study drug.
- Contact the study doctor if you find you or your child have any questions about the study after you sign this form.
- Your child and/or your child's partner must use reliable forms of contraception during the study and for 60 days after taking the study drug. If your child or your child's partner becomes pregnant while he/she is in the study, be sure to tell the study doctor as soon as possible.

What are the benefits of being in this study?

There is no guarantee that your child will receive any benefits. However, your child will be helping others by contributing to medical research. You and your child may feel that you are benefiting in the following ways:

- Taking part in the study will be at no cost to you or your child. Your child's condition will be checked as long as your child's participation in the study lasts. However, services provided and evaluations carried out as part of the study should not be seen as a substitute for a careful evaluation, ongoing medical care, or follow-up by your child's primary doctor.
- The study drug may help to relieve your child's symptoms.
- By volunteering for the study your child and the whole family may learn more about migraine in general and your child's migraine pattern, associated symptoms, triggers, and risks.

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 prevent and treat migraine attacks in adults. By the end of August 2021, approximately 5661 people have received 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 muscle enzymes (an indication of possible muscle injury) have been infrequently reported in studies with rimegepant. However, a causal relationship between rimegepant and these laboratory findings has not been found at approved doses. Upper respiratory tract infection, cold-like symptoms, nasal sinus swelling, urinary tract infection, flu, back pain, bronchitis, nausea, abdominal pain/indigestion, dizziness, joint pain, diarrhoea, constipation, and headache were also infrequently reported.

Allergic reaction risks:

With any medication, there is a small but real risk of allergic reactions that can be life-threatening or 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 your child has an allergic reaction, you must get emergency medical care immediately.

Animal studies have been performed with high doses of rimegepant (approximately 30 to 200 times higher than the dose of rimegepant used in this research study) to try to predict what type of side effects might occur in humans taking rimegepant. In some of these animals, vomiting and effects on red blood cells, liver, muscle and lungs were noted. No effects were noted on the embryos of rats exposed to rimegepant who became pregnant. While animal studies do not always predict human response to drugs, the results from these studies in animals and other studies in humans supports the safety of this research study with Rimegepant.

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

What are the possible risks of study procedures?

Your child 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, inflammation of 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 the electrodes (small sticky patches) that are used.
- Questionnaires: The questionnaires used in this study may be upsetting. Your child does not need to answer any questions that he/she is not comfortable with. If your child decides not to complete certain questionnaires, he/she may not be eligible to continue participation in this study. If your child is having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form.
- If your child is feeling overwhelmed, or your child want to hurt himself/herself , 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 your child may attempt suicide, or your child have seriously hurt , it's an emergency. You should call 999 and ask for an ambulance.

- If your child receives placebo (the inactive drug) as part of this study, his/her symptoms may not improve.
- Your child's study doctor may discuss sensitive topics such as mental wellbeing and suicide prevention and your child can choose not to take part if he/she is 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. If there are significant new findings during this course of your child's participation in this research study or other ongoing research your child's study doctor will provide you and your child with the relevant information.

Additionally, there may be unknown risks to a pregnancy, embryo, or foetus if your child or your child's female partner becomes 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 your child is pregnant, planning to become pregnant, or breastfeeding a child, she cannot take part in this study.

Before entering the study, a serum (blood) pregnancy test will be done for all girls who are able to become pregnant (i.e. those who have had their first menstrual period). This test might not detect an early pregnancy.

The only certain way not to become pregnant is to not have sex. If your child chooses to have sex during the study, she must use acceptable methods of contraception while she is taking part in this study and for 60 days after her last dose of study drug. If your child is already using a method of contraception, the study doctor or study staff will discuss with her whether her current method of contraception is acceptable for use during this study.

Methods of acceptable contraception include:

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

Your child should not take the study drug if she is pregnant. If during the study your child becomes pregnant, you should tell the study doctor immediately, and she will be withdrawn from the study. She will be asked to complete the final procedures and assessments to terminate the study.

Males

If your child chooses to have sex during the study, he and his female partner should be compliant with acceptable methods of contraception that may include:

- abstinence
- 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 an IUD (with or a without hormone release system) used since at least 4 weeks prior to study drug administration
- the simultaneous use of a male condom and, for the female partner, a diaphragm or cervical cap with intravaginal applied spermicide.

If your child's partner becomes pregnant, the Sponsor may want to receive updates on the progress of the pregnancy and its outcome. If your child agrees to this, your child's 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 XXXXX.

What if there are new findings?

If new findings that would affect your child's safety and willingness to participate in the study are identified while your child is in the study, you and your child will be told as soon as possible so your child can decide whether to leave the study or continue. If your child continues, you and your child will be required to sign a new informed consent/assent form.

What other options are available if my child does not take part in this study?

Your child does not have to take part in the study to treat his/her migraine. There are treatments available for migraine, including prescription and non-prescription medications, as well as drugs approved by the MHRA (The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the United Kingdom 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 treatments with you and your child.

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

You should also contact your child's GP to ask about other research currently being done in the treatment of 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 my child be paid for being in the study?

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

To thank your child for being in the study, they will be given a temporary tattoo of a red fox (the study logo) at each visit. They will receive a canvas bag at the baseline visit, and, depending upon their age, a game board and stickers upon completion of each study visit, and sunglasses or blue light blocking glasses when they complete the study.

What if my child 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 [insert telephone].

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

What are the benefits of being in this study?

There is a chance that the study drug used in the study may help your child condition. At this time it is not 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 ensure your participation will not affect any coverage you have.

Can my child leave the study after it has begun?

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

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

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

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

What will happen to the samples that my child provides?

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

What happens when this study stops?

When the study stops, your child will be under the care of his/her GP, who will decide the best way to treat your child's migraine. The study drug will no longer be available to your child. Your child may be eligible to participate in a long-term safety study of rimegepant. You and your child should talk to the study doctor about this possibility.

Will my child's records be kept private?

For your child 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 website will 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 European Clinical 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 for your child to be in a research study you can call the following contact point.

Study Doctor/Contact Name: insert name

Daytime Telephone Number(s): insert telephone number

24-hour Contact Number(s): insert telephone number

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

Insert PALS (Patient Advice and Liaison Service) details

or for non-NHS sites the Private institutional contact details <Insert Telephone Number>

Parental/Legal Representative Master Informed Consent Form

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:	<Insert>
Telephone number (s) **Daytime:** **After hours:**	 <Site phone number> <Site phone number>
Participant number:	Insert number

Consent to Participate:
By signing this informed consent form, I agree to the following:

	Please initial each box
I have read and I understand this informed consent form 10 Dec 2021 (version 5.1.0) for the above study.	
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 my child taking part in this study as described in this informed consent form.	
I understand that there is no guarantee that my child will receive any benefits from taking part in this study.	
I freely consent for my child to be treated with rimegepant or placebo under the study doctor's care.	
I confirm that all information that I have given about my child's medical history is correct to the best of my knowledge.	
I agree to my child's GP being informed of his/her participation in the study.	
I agree to ask questions about my child's health, take blood and urine samples and any examinations by the study doctor.	
I have read and understood that I have the right to withdraw my child's participation from the study at any time without giving any reason and	

without losing any rights. No more data will be collected but the data already collected will be used.	
I will tell the study doctor if I decide to withdraw my child from the study so that his/her participation may end in an orderly manner and his/her future care can be discussed.	
I understand that I/my child will be told of any new information that might relate to his/her willingness to continue in the study.	
I will tell the study doctor if my child has 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.	
My consent for my child to participate in this study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study.	
I understand that my child's medical notes and records may be looked at by authorised persons from Biohaven or its representatives, from the local health authority or from regulatory authorities, where it is relevant to my child's taking part in this research. I give my permission for these people to have access to my child's records. I understand that if I withdraw my consent for my child's participation prematurely that my child's records may need to be accessed after I withdrawal in order to verify data collected while my child was in the study".	

The study staff will give you a copy of this signed consent form for your records.

- I agree that my child's GP be informed about my participation in this clinical research study (tick Yes or No and initial on the appropriate line).

☐ Yes _____ ☐ No _____

_____
Name of parent or legal guardian (print)

_____ _____
Signature of parent or legal guardian Date (dd/Mmm/yyyy)

_____

Name of child (print)

_____
Name of study doctor or person administering consent (print)

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

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 staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions to the study staff.

_____
*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 Clinical Practice: Consolidated Guidance.

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 research project.

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 keeping your 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 information about your health from central NHS records, your hospital, your GP. If you do not want this to happen, 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.

Consent to the Collection, Processing, and Use of Personal Data

By signing below, I agree that:

(1) My child's personal data, including sensitive personal data, can be collected, used, and archived for purposes of carrying out the study as described in this Privacy Notice.

(2) My child's personal data, including sensitive personal data, can be transferred to and shared with other companies both within and outside of the European Economic Area (EEA), including countries that may not have the same level of data protection as the EEA, as described in this Privacy Notice.

(3) My child's coded personal data may be retained and used for future research into my medical indication.

This consent is valid unless you change your mind and provide a written notice to the study doctor.

_____
Name of participant (print)

_____
Name of parent/guardian of participant (print)

_____ _____
Signature of parent/guardian of participant Date (dd/Mmm/yyyy)

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 staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions to the study staff.

_____
*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 Clinical Practice: Consolidated Guidance.