PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:	**A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Tolerability of Rimegepant for the Prevention of Migraine in Adults with a History of Inadequate Response to Oral Preventive Medications**
Protocol Number:	**BHV3000-407**
EudraCT Number:	**2022-001176-34**
Sponsor:	**Biohaven Pharmaceuticals, Inc.** **215 Church St, New Haven,** **CT 06510, USA**
Investigator: ***(Study Doctor)***	**«PiFullName»**
Site address:	**«PiLocations»**
24-hour Telephone Number:	**«IcfPhoneNumber»**

INTRODUCTION

You have been invited to participate in a research study of a new medicinal product.

This research study is studying Rimegepant as a possible therapy for the preventative treatment of migraine in adults with a history of inadequate response to past oral migraine preventative treatments.

Your participation in this study is voluntary and the decision whether to participate or not is entirely yours. This decision will not affect your relationship with your doctor or affect your current or future medical treatment. If you want to, please discuss this study with your friends and family. Ask the investigator (the study doctor) about anything that is not clear or for any additional information you may require.

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have recurrent migraine headaches and other oral preventative medications have not worked for you or are not an option for you to take.

Migraine is a debilitating disorder that affects approximately 15% of the population. Migraines are characterised by recurring attacks lasting 4 to 72 hours with multiple symptoms, including pulsating (throbbing) headaches of moderate to severe pain that could be associated with nausea or vomiting, and/or sensitivity to sound (phonophobia) and sensitivity to light (photophobia).

The purpose of this research study is to:

- Test the effectiveness of Rimegepant compared with placebo in the prevention of migraine in subjects who:
    - Are 18 to 65 years old
    - Have at least 1 year of migraines before the age of 50
    - Have migraine attacks which last about 4-72 hours, if left untreated
    - Have been unsuccessful with or unable to take other oral medications for the prevention of migraine

This is a double-blind study, which means neither you nor the study doctor will know if you were assigned Rimegepant or placebo. In the event of an emergency, the study doctor can get this information.

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

About 1000 subjects will participate in this study and approximately 600 subjects will receive Rimegepant or matching placebo.

Your participation in this study will last approximately 18 weeks and will include approximately 8 study visits to the study site.

- The first part of the study is called the **Observation phase** and it is scheduled to last for a total of 4 weeks (2 site visits).
- Study eligibility will be reviewed by study staff who will determine if you are eligible and can continue in the study.
- The second part of the study is called the **Double-blind study treatment phase** and it is scheduled to last for a total of 12 weeks (5 site visits).
- The last 2 weeks of the study is called the **Follow-up phase** (1 site visit).

This study will use competitive enrollment. This means that when a target number of subjects begin the double-blind treatment phase, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of subjects has already begun the study.

Washout Period: If you are taking a medication that is not permitted while on this study, you may be asked to stop taking that medication. This is called a washout period, during which the effects of these medications leave your body.

STUDY VISITS AND PROCEDURES

Observation Phase

The observation phase will have two scheduled clinic visits: Screening and, Pre-Randomisation. All two visits must be completed in person.

Screening Visit:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent form. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Review of your medical history.
- You will be asked about your typical migraine symptoms, frequency, severity and how your migraines are usually treated.
- You will be asked about past and current medications and supplements you are taking or have taken.
- A physical examination will be performed.
- Your weight and vital signs (blood pressure, heart rate, breathing rate and temperature), and height (only assessed at the Screening Visit) will be measured.
- You will have blood samples collected (approximately 15 ml) for laboratory tests.
    - You should not eat for at least 8 hours prior to taking these blood tests.
    - Additional diagnostic testing will be completed including blood tests to assess your general health, the wellness of your kidneys and liver, and to look for the presence of specific viral infections (Hepatitis A, B, and C and HIV). The study doctor may be required by law to report the result of these tests to the local health authority.
- A urine sample will be collected for:
    - A drug screen to test for drugs of abuse. The result of the test must meet study entry criteria evaluated by the study doctor for you to participate in this study.
    - If you are a woman of childbearing potential (a woman who may be able to become pregnant): this will include a urine pregnancy test. The result of the pregnancy test must show that you are not pregnant for you to qualify to participate in this study.
- Your heart function will be assessed with an electrocardiogram (ECG - a test that measures and records the electrical activity of your heart).
- You will be asked to complete a questionnaire about any thoughts of suicide you may have had and any suicidal actions (Columbia-Suicide Severity Rating Scale).

- You will be asked how you are feeling and if you had any important medical events recently.
- You will be given a concomitant medication paper log (sometimes referred to as a paper diary) to complete at home to record the medications or supplements you take.
- You will be provided an electronic diary (eDiary) and will be trained on how to use the eDiary by the study staff. Your use of the handheld device is required for you to be part of this study. Your 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.
- Every day, during the Observation phase, the eDiary will alarm with a reminder to complete the headache report.
- During the observation phase, when you experience a migraine, you should use the eDiary to report your migraine and any medications you may have taken to treat the migraine.
- You will not receive study drug at this visit.

Pre-Baseline Visit:

- You will be asked about all medications and supplements you are currently taking or you have taken since the Screening Visit. Study staff will review this list of medications with you.
- You will have blood samples collected (approximately 15 ml) for laboratory tests
    - You should not eat for at least 8 hours prior to taking these blood tests.
    - If you are a woman of childbearing potential: this will include a serum pregnancy test. The result of the pregnancy test must show that you are not pregnant for you to qualify to participate in this study.
- You will be asked how you are feeling and if you had any important medical events since your last visit.
- Please record the use of any medication or supplements on the concomitant medication log.
- You will review the daily eDiary response with study staff to ensure there are no errors.
- You will not receive study drug at this visit.

Double-Blind Study Treatment Phase:

During the double-blind study treatment phase there are a total of five visits: (Baseline/randomisation, Week 2, Week 4, Week 8 and week 12/EOT). The baseline and week 12/EOT visits must be completed in person. You will be scheduled to return to the study site to complete the Baseline Visit approximately 24-28 days after completion of the Screening Visit.

At the Baseline visit, eligible subjects will be dispensed double-blind study drug (either rimegepant or placebo), to be taken every other day throughout the double-blind study treatment phase.

During the double-blind study treatment phase, when you experience a migraine, you should use the eDiary to report your migraine and any medications you may have taken to treat the migraine. The eDiary will ask you questions:

- Every other day, the eDiary will alarm with a reminder to take study drug, starting with your first dose at the baseline (randomisation) visit. The eDiary will provide you with reminders to take study drug on your "scheduled dosing days".
- Every day, the eDiary will alarm with reminder to complete the headache report and the Patient Global Assessment (PGA). This questionnaire will ask about your current condition and ways your migraine condition affects you.
- Every 7 days, the eDiary will alarm with a reminder to complete the Migraine Functional Impact Questionnaire (MFIQ) within the eDiary, starting at the Baseline Visit. This questionnaire will help understand how migraine affects your day-to-day activities.
- You will continue to complete your concomitant medication paper logs if you are taking any medications or supplements for any reason. Please record any medication use other than study drug within this paper diary. Study staff will review use of all medications and supplements you currently are taking or have taken throughout the course of the study.

<u>Baseline (Randomisation) Visit:</u>

The following tests and procedures will be performed:

- Review of any changes in your health since your last visit.
- Please record the use of any medication or supplements on the concomitant medication log. Study staff will review this list of medications with you.
- A physical examination will be performed.
- Your vital signs and weight will be measured.
- If you are a woman of childbearing potential: A urine sample will be collected for a pregnancy test. The result of the pregnancy test must show that you are not pregnant for you to continue to participate in this study.
- You will be asked about how you have been feeling since your last visit and if you had any important medical events since your last visit.
- The study doctor and study staff will ask that you complete the following questionnaires:
    - You will be asked to complete a questionnaire about any thoughts of suicide you may have had and any suicidal actions (Columbia-Suicide Severity Rating Scale).
    - You will be asked to complete the paper questionnaire called Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headaches on your daily activities.
    - You will be asked to complete a paper questionnaire called Migraine Interictal Burden Scale (MIBS) to assess the impact recurring migraines have on your quality of life between migraine attacks.
    - You will be asked to complete a paper questionnaire called Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraines and your ability to work and perform regular activities.

  - You will be asked to complete a paper questionnaire called Headache Impact test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.
  - You will be asked to complete an electronic questionnaire called the Patient Global Assessment on the eDiary each day, starting at the Baseline Visit. This questionnaire will ask about your current condition and ways your migraine condition affects you.
  - You will be asked to complete an electronic questionnaire called the Migraine Functional Impact Questionnaire (MFIQ) on the eDiary every 7 days, starting at the Baseline Visit. This questionnaire will help understand how migraines affects your day-to-day activities.
- If you are eligible for the study, the study doctor and study staff will give you a supply of study drug (2 "wallets"- A "wallet" is a storage envelope for your study drugs) and will tell you how and when to take the study drug. You will also be provided dosing instructions.
- **Please take your first dose of study drug while you are at the clinic for the baseline visit.**

<u>Week 2, Week 4, and Week 8 Visits:</u>

The following tests and procedures will be performed at Weeks 2, 4 and 8:

- Review of any changes in your health since your last visit.
- You will continue to complete your concomitant medication paper logs if you are taking any medications or supplements for any reason. Please record any medication used other than the study drug within this paper diary. Study staff will review use of all medications and supplements you currently are taking or have taken throughout the course of the study.
- A physical examination will be performed.
- Your vital signs and weight will be measured.
- If you are a woman of childbearing potential: A urine sample will be collected for a pregnancy test. The result of the pregnancy test must show that you are not pregnant for you to continue to participate in this study.
- You will be asked about how you have been feeling since your last visit.
- Blood sample collection for laboratory tests (approximately 15 ml) – *week 4 only.*
- At every visit, you must bring:
  - Your eDiary for review of completeness.
  - Your Concomitant Medication Paper Diaries for review of completeness.
  - Your Study drug (used and unused wallets).
- You will be asked to complete a questionnaire about any thoughts about suicide you may have had and any suicidal actions (Columbia-Suicide Severity Rating Scale) – *week 4 only.*
- You will be asked to complete the paper questionnaire called Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities. – *Week 4 and Week 8 only.*

- You will be asked to complete a paper questionnaire called Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraines have on your quality of life between migraine attacks. – *week 4 and week 8 only.*
- You will be asked to complete a paper questionnaire called Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities. – *Week 4 and Week 8 only.*
- You will be asked to complete a paper questionnaire called Headache Impact Test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time. – *Week 4 and Week 8 only.*
- Used study drug will be collected, please make sure to return empty wallets and any study drug not taken.
- Additional study drug will be dispensed.

Week 12 or Double-Blind End of Study Treatment Visit:

The following tests and procedures will be performed at Week 12 or if you end your participation early in the double-blind study treatment phase for any reason:

- A physical examination will be performed.
- Your vital signs and weight will be measured.
- You will have blood samples collected (approximately 15 ml).
- If you are a woman of childbearing potential: A urine sample will be collected for a pregnancy test.
- Your heart function will be assessed with an electrocardiogram (ECG - a test that measures and records the electrical activity of your heart).
- You will be asked how you are feeling and if you had any important medical events since your last visit.
- You will continue to complete your concomitant medication paper logs if you are taking any medications or supplements for any reason. Please record any medication used other than the study drug within this paper diary. Study staff will review the medications and supplements you are currently taking or have taken throughout the course of the study.
- Your eDiary will be reviewed and returned.
- You will return the used and unused study drug wallets.
- You will be asked to complete a questionnaire about any thoughts about suicide you may have had and any suicidal actions (Columbia-Suicide Severity Rating Scale).
- You will be asked to complete a paper questionnaire called Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities.
- You will be asked to complete a paper questionnaire called Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraines have on your quality of life between migraine attacks.
- You will be asked to complete a paper questionnaire called Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.

- You will be asked to complete a paper questionnaire called Headache Impact Test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.

Follow-up Visit (Week 2)

- Review of any changes in your health since your last visit.
- A physical examination will be performed.
- Your vital signs and weight will be measured.
- If you are a woman of childbearing potential: A urine sample will be collected for a pregnancy test.
- You will be asked how you have been feeling since your last visit.
- Collect and review the completed concomitant medication paper logs.

Study Treatment:

The study drug is Rimegepant or matching placebo. Rimegepant is a disintegrating tablet (a tablet that is taken without water and dissolves in the mouth), 75 mg taken orally.

During the double-blind study treatment phase, you will be randomly assigned by chance (like the flip of a coin) to receive either Rimegepant or placebo (inactive substance). You will have a 50% chance (1 in 2) of receiving Rimegepant and a 50% chance (1 in 2) of receiving placebo. This is a double-blind study, which means neither you nor your study doctor (Investigator) will know to which of the study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.

During the double-blind study treatment phase, you will be required to take 1 tablet of study drug every other calendar day, even if you don't have a migraine. These are considered "scheduled dosing days". You cannot take study drug on the days between scheduled dosing days ("non-scheduled dosing days"). You are not allowed to take study drug to treat an acute migraine. Study drug should be taken for the first time at the Baseline Visit.

After Study Treatment:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over. This study drug may be available by prescription for acute treatment of migraine and/or migraine prevention in the United States of America and some other countries around the world.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Attend each scheduled visit.
- Tell the study doctor and study staff about any change in your health and medications (including over-the-counter medications and supplements).
- Take the study drug as instructed by the study doctor and study staff.
- Store the study drug as instructed by the study doctor and study staff.
- Return all unused study drug (including unused wallets) to the study staff. Bring the unused study drug (including unused wallets) with you to every site visit.

- Complete the questionnaires using your handheld device at ALL of the appropriate time points.
- Complete the paper diaries as per instruction. Bring the paper diaries with you to every site visit for review.
- Complete the eDiary as per instruction.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Participation in a clinical research study involves some unforeseeable risks or side effects that could occur.

Risks associated with the study drug:

Studies in Humans

Rimegepant (sold as Nurtec ODT and Vydura) is an approved treatment for preventive treatment of migraine in adults. As of February 2022, approximately 5,800 individuals have used Rimegepant while participating in a clinical study.

The most common adverse effect possibly related to the use of Rimegepant for the prevention of migraine is nausea (1.4%). Most cases of nausea have been rated as mild or moderate. Serious allergic reactions (also called, "hypersensitivity reactions"), including those causing shortness of breath and/or severe rash, have occurred uncommonly (much lower than 1%).

To date, more than one dose of Rimegepant has been given to 2,471 adults who participated in one of two different clinical studies (BHV3000-201 and BHV3000-305). Below, are detailed summaries of the most common adverse outcomes reported during the conduct of those two studies.

- **Table 1** summarizes the most common adverse outcomes by body system and rate of occurrence (minimum 2%), and
- **Table 2** summarizes the most common "severe" adverse outcomes by body system and rate of occurrence (minimum of more than 2 subjects).

The adverse outcomes listed in Table 1 and Table 2 are not necessarily associated with the dosing of Rimegepant. In fact, the types of adverse outcomes reported, and the rate of occurrence of those adverse outcomes, have been generally similar between adults who were treated with Rimegepant versus adults who received placebo while participating in a Rimegepant clinical study (data not shown).

Table 1: Most Common Adverse Events and Rates of Occurrence– Adults Receiving Multiple Doses of Rimegepant as Subjects in Clinical Studies (minimum, 2%)

Body System	Adverse Event Term	Number of Subjects with Event (N=2,471) (%)
Infections	Upper respiratory tract infection (a cold)	209 (8.5)

	Nasopharyngitis (cold-like symptoms)	170 (6.9)
	Sinusitis (swelling of the nasal sinuses)	114 (4.6)
	Urinary tract infection	96 (3.9)
	Influenza (flu)	84 (3.4)
	Bronchitis (swelling in the large airways in the lungs)	63 (2.5)
Gastrointestinal	Nausea	67 (2.7)
Musculoskeletal	Back pain	86 (3.5)
	Arthralgia (joint pain)	55 (2.2)
Nervous	Dizziness	53 (2.1)

Table 2: Most Common Severe Adverse Outcomes and Rates of Occurrence– Adults Receiving Multiple Doses of Rimegepant as Subjects in Clinical Studies (minimum, more than 2 subjects)

Body System	Adverse Event Term	Number of Subjects with Event (N=2,471) (%)
Nervous	Migraine	4 (0.2)
Blood	Anemia (low red blood cell count)	3 (0.1)
Infections	Influenza (flu)	3 (0.1)
Musculoskeletal	Back pain	3 (0.1)
	Osteoarthritis (pain and swelling due to degeneration of a joint[s])	3 (0.1)
Renal (kidneys)	Nephrolithiasis (kidney stone)	3 (0.1)
Respiratory (lungs)	Asthma	3 (0.1)

Note: *A "severe" adverse outcome is defined as an event that results in: 1) Significant worsening in the health status of an individual, 2) Inability of the individual to complete usual daily activities, or 3) Otherwise requires major medical action to treat the individual's medical condition.*

Allergic reaction risks:

With any drug, there is a small but real risk of allergic reactions that can be life-threatening or fatal. Severe reactions with any drug can include difficulty breathing and a rash and can occur days after administration.

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.

Studies in animals

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. There was no evidence of adverse effects on the development of fetuses in pregnant rats and rabbits up to the maximum evaluated dose of Rimegepant (exposures 46- and 10-times the recommended human dose, respectively). While animal studies do not always predict human response to drugs, the results from these studies in animals and other studies in humans support the safety of this research study with Rimegepant.

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, 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 or gel that is 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, you can call 999 or The Samaritans on 116 123, calls are answered 24 hours a day with a skilled, trained counsellor.
- If you receive placebo (the inactive substance) as part of this study, your symptoms may not improve.

UNFORESEEN RISKS

Although Rimegepant [NURTEC ® ODT, Vydura] is approved by the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), and UK Medicines and Healthcare Products Regulatory Agency (MHRA) for the acute and preventive treatment of migraine attacks in adults. As of 26-August-2022, approximately 6,036 people have received rimegepant at any dose while participating in migraine or trigeminal neuralgia studies. The dosing of Rimegepant of more than 18 days per month (month is defined as 28-days) is investigational and is not permitted in this or other ongoing studies. There may be other risks that are unknown when it is taken alone or in combination with other drugs. Any risk or side effect, rare or not, may worsen and become severe or life-threatening. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become severe or life threatening.

If you experience any new symptoms, contact your study doctor or study staff at the phone number listed on the first page of this form.

If there are significant new findings during your participation in this research study or other ongoing research, your study doctor will provide you with the relevant information.

Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant. If you are a woman who may be able to become pregnant

and you suspect you may be pregnant while participating in the study, you are to not take any further doses of study medication and immediately contact your study doctor.

Electronic Devices:
As part of this study, some of your personal information will be transferred electronically via the Internet. While every effort will be made to protect the confidentiality of your information, electronic transmissions via the Internet are not necessarily secure from interception, and absolute confidentiality cannot be guaranteed. We, as the Sponsor of the study, and our contracted partners should not be collecting nor sharing any personal identifying information (such as name, address, telephone number, or government-issued identification number) throughout the conduct of this study.

PREGNANCY / BIRTH CONTROL REQUIREMENTS / BREASTFEEDING

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

Except abstinence, other methods of contraception are not 100% effective. If you think you may have become pregnant, even though you correctly used contraception in accordance with the study plan, you should contact the study doctor or the study staff immediately (see telephone number at the first page of this form).

Females (sex designation at birth):
In order to reduce the risk of pregnancy, all women with the potential to become pregnant (females who have had a menstrual period, are not post-menopausal, and have not had a surgery that prevents future pregnancy, such as: a hysterectomy [uterus surgically removed], or surgery in which both ovaries were removed, or surgery in which both "tubes were tied") with male sexual partner(s) are required to use **two** methods of contraception (including at least one highly effective method and one additional method) while you are participating in this study (starting time of written consent) and for 60 days after taking the last dose of study drug. In this study, recognized highly effective methods of birth control include approved birth control pills, intrauterine devices (IUDs), and prior history of vasectomy (in males), etc. Other acceptable methods of birth control include barrier methods such as male or female condoms, diaphragm, and sponge with spermicide.

The study doctor or study staff can further discuss details with you.

If you become pregnant while you are participating in this study or within 60 days after you have stopped taking the study drug, you should notify your study doctor as soon as possible. The study drug will be stopped and your participation in this study will be ended. Study staff will collect information about the pregnancy, its outcome, and the health of the child after birth.

Males (sex designation at birth):
In order to reduce the risk of pregnancy, male participants with female sexual partner(s) with the potential to become pregnant (females who have had a menstrual period and are not

post-menopausal, and have not had a surgery that prevents future pregnancy such as a hysterectomy [uterus surgically removed], or surgery in which both ovaries were removed, or surgery in which both "tubes were tied") are required to use **two** methods of birth control (including at least one highly effective method and one additional method while participating in this study and for 90 days after taking the last dose of the study drug. In this study, examples of recognized highly effective and otherwise acceptable methods of birth control are provided above (See *Females [sex designation at birth]*). Notably, vasectomy is considered as one highly effective method of birth control, and therefore, one additional form of birth control is required throughout the course of the study.

The study doctor or study staff can further discuss details with you.

If your female partner becomes pregnant while you are participating in this study or within 90 days after you have stopped taking the study drug, you should notify your study doctor as soon as possible. At that time the study doctor may seek the pregnant woman's permission to review her medical records and the infant's medical records after delivery, in the form of a separate consent form. The study doctor will share the information about your pregnant partner and the baby with the study sponsor to help understand the effects, if any, that the study drug may have on the pregnancy and the child.

If you are a male, you must not donate sperm until 90 days following the last dose of study drug.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your migraines. Your options may include:

- Prescription and non-prescription medications such as aspirin, acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen, combination pain relievers with aspirin, acetaminophen and caffeine, opioids, triptans, and ergotamine and Botox. Some of these drugs are approved by the FDA specifically for the treatment of migraine.

Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

BENEFITS

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

You will not have to pay to participate in this study. Any travel and accommodation costs will be refunded if you provide receipts subject to prior approval from the Sponsor or Sponsor delegate. You will not receive any other payments for participating in this study.

ETHICS AND REGULATIONS OF THE STUDY

This study was given a favourable ethical opinion by the [*insert name of Research Ethics Committee*] Research Ethics Committee.

PROCESSING OF PERSONAL DATA FOR THE STUDY

WHICH PERSONAL DATA WILL BE COLLECTED AND WHY?

The conduct of this research study aiming at developing a new treatment requires the collection and the analysis of your personal data (also called processing). This will be performed under the responsibility of the sponsor, Biohaven Pharmaceuticals, Inc. represented by its current legal representative, and in accordance with the United Kingdom's Data Protection Act 2018 and the European Union's General Data Protection Regulation (GDPR).

Your personal data that will be collected will consist in:

- Some of your background information, such as your gender, your age, your ethnicity and
- All the medical information relevant for the study, including your medical history, your medical condition, and the results of your examinations performed during the study.

These data will be referred to as "personal-study data" throughout this document.

Only the information necessary to conduct the research and justified in the study protocol will be processed. All this information will be treated with the greatest confidentiality during the study and beyond.

HOW WILL MY DATA BE PROTECTED?

Your information will be directly collected by the study doctor and the study staff. To ensure the transfer of your data to the sponsor or to the companies working for the sponsor in a confidential manner, they will only be identified by your unique code number.

The sponsor will use security measures that will protect your personal-study data from destruction, loss, alteration, unauthorised access, or disclosure. Information collected during this study will be processed and saved using validated informatic tools. The access to your personal data will be restricted to duly authorised and trained personnel.

For the needs of the study, your data will be sent to other countries. The sponsor will ensure that the level of security of these transfers will comply with applicable personal data protection legislation.

WHO WILL HAVE ACCESS TO MY DATA?

Only authorised staff who are involved in the study conduct, analysis, reporting and regulatory submission will access to your information. This access will be restricted to your coded data.

An access to your non-coded data, including your medical record, will be necessary for verification of the study procedures and/or data quality, without violating the confidentiality of the information, to the extent permitted by the applicable laws and regulations. By consenting to participating in this study, you therefore authorise this access by:

- individuals or companies involved in the study conduct and mandated by the Sponsor, and
- relevant regulatory authorities.

In addition, if you agree, your study doctor will inform your family doctor that you are taking part in this study and update him/her about your health status.

WHAT ARE MY RIGHTS REGARDING MY PERSONAL-STUDY DATA?

You are entitled to ask the study doctor what data are being collected about you and how those data will be used in connection with the study, you have the right:

- To request access and rectification of your data;
- To obtain your medical record;

You can exercise these rights by writing to your study doctor.

Please be informed that the data collected for the purpose of this study cannot be erased as it will jeopardize the study results.

If you wish to exercise your rights or have any questions, comments, or complaints about how your information is stored and processed in this study, you should firstly contact your study doctor, and after then the Sponsor.

If you wish to raise a complaint on how your personal data has been handled, you can contact the Sponsor's Data Protection Officer at ricardo.garvao@biohavenpharma.com who will investigate the matter. If you are not satisfied with their response or believe the Sponsor is processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

WHAT WILL HAPPEN TO MY PERSONAL-STUDY DATA AFTER THE STUDY?

After the study, the results will be sent to regulatory authorities and appear in clinical study registries.

The results may also be published or presented at scientific meetings.

In any case, they will not include information that can directly identify you.

Then your personal-study data (coded with your unique code) will be retained for 25 years and will be destroyed thereafter. This will also apply in the case if you decide to stop your study participation.

A description of this clinical study will be available on the register found in the internet link http://www.ClinicalTrials.gov, and in the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu). These registers will include a summarised description of the protocol of the study and, once available, a link to the publications of the results of the study. They will not include any information that can identify you or any other participant of this study. You can search these web sites at any time.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. The sponsor of this study has taken out an insurance policy with the company AHT Insurance, A Baldwin Risk Partner under the policy number 36064415 to cover all patients who take part in this study. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalisation is required, alert the treating doctor or clinician that you are participating in this research study.

VOLUNTARY PARTICIPATION / VOLUNTARY WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the Sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study, including failure to complete the electronic diary (and paper diaries) or failure to show up at the site for study visits;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons, including competitive enrollment - the target number of subjects has entered the study.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

Primary Health Care Provider Notification Option

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒ Yes (If yes, please complete the information below)

❒ No, I do not want the study doctor to inform my primary care physician/ specialist of my participation in this study.

❒ I do not have a primary care doctor/ specialist

❒ The study doctor is my primary care doctor/ specialist

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT FORM

Study Title:	**A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Tolerability of Rimegepant for the Prevention of Migraine in Adults with a History of Inadequate Response to Oral Preventive Medications**
Protocol Number:	**BHV3000-407**
EudraCT Number:	**2022-001176-34**
Sponsor:	**Biohaven Pharmaceuticals, Inc.** **215 Church St, New Haven,** **CT 06510, USA**

Please initial the 'Yes' column if you agree or initial the 'No' column if you do not agree:

1) I confirm that I have read and understand the Information Sheet specific for UK V2.0 dated 28 OCT 2022 for the above study and have had the opportunity before today to discuss the study and ask questions. My questions have been answered to my satisfaction and I have had time to decide whether I wish to take part.	**Yes**	**No**
2) I understand that my taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	**Yes**	**No**
3) I understand that sections of any of my medical notes may be looked at by responsible individuals from the Sponsor, its affiliates and their associates or legitimate third-party contractors, consultants, health/regulatory authorities or other approving bodies, or ethics committees where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	**Yes**	**No**
4) I give permission for my primary physician to be informed about my taking part in the study.	**Yes**	**No**
5) I agree to my personal data being used for the purposes of the study, and to my data being shared with the Sponsor, third party contractors and consultants, and heath/regulatory authorities and other authorised entities both within and outside this country, as described in the Information Sheet. I acknowledge that this may involve my data being transferred to countries outside UK which may not provide the same standard of legal protection for my data.	**Yes**	**No**
6) I agree to take part in the above study.	**Yes**	**No**

Name of patient	Date	Signature

For any impartial witness(es)

Please initial the 'Yes' column if you agree or initial the 'No' column if you do not agree:

1) I have received and read the Information Sheet and Consent Form and any other written information provided to the patient/parent/legal representative.	**Yes**	**No**
2) I have attended all discussions between the investigator/doctor or clinician /nurse and the patient /parent/legal representative.	**Yes**	**No**
3) By signing, I attest that the information provided was accurately explained to, and apparently understood by, the patient, and that informed consent was freely given.	**Yes**	**No**

Impartial witness(es)	Date	Signature