# Participant Information Sheet/Consent Form

**Interventional Study** - *Adult providing own consent*

| | |
|---|---|
| **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 |
| **Short Title** | Rimegepant for Prevention of Migraine |
| **Protocol Number** | BHV3000-407 |
| **Project Sponsor** | Biohaven Pharmaceuticals, Inc. |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Marc Russo MBBS DA (UK) FANZCA, FFPMFANZCA |
| **Associate Investigator(s)** | Dr Cillian Suiter, Dr Ulrich Liedvogel |
| **Location** | 220 Denison Street Broadmeadow, NSW |

## Part 1 What does participation involve?

### 1 Introduction

You have been invited to participate in a clinical research study. This research study is studying the effects of a potential new treatment called "rimegepant" in a group of adults living with recurrent migraine. Rimegepant has been previously studied at the dose and dosing frequency being used in the current trial (75 mg, one tablet every other calendar day), and has been approved by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for the preventive treatment of migraine in adults. The current study is investigating the potential benefit of rimegepant in a group of adults who have experienced inadequate response to other preventive migraine medications due to prior lack of benefit, intolerable side effects, or other safety concerns. Other possible preventive oral (by mouth) migraine medications include, but are not limited to:

- Valproic acid
- Gabapentin
- Topiramate
- Amitriptyline
- Candesartan
- Lisinopril
- Certain beta-blockers (such as atenolol and metoprolol)
- Certain serotonin-norepinephrine reuptake inhibitors (such as desvenlafaxine and venlafaxine)
- Certain calcium-channel blockers (such as flunarizine and verapamil)

The current study is being conducted for Biohaven (a pharmaceutical company based in Connecticut, U.S.A.). The study doctors and staff conducting this trial are being paid by Biohaven.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the participant to take part in this research project.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part in this research project.

If you decide you want to take part in this research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to taking part in the research project
• Consent to having the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

## 2 What is the purpose of this research?

Migraine is a debilitating disorder that affects about 4.9 million Australians. Migraine are characterised by recurrent attacks lasting 4 to 72 hours with multiple symptoms, including throbbing (pulsating) headaches of moderate to severe pain that could be associated with nausea or vomiting, and/or sensitivity to sound and sensitivity to light.

The purpose of this research project is to test the effectiveness of rimegepant compared to placebo for the prevention of migraine in participants who:

- Are 18 to 65 years old
- Have had migraine for at least 1 year before the age of 50
- Have migraine attacks that last about 4 to 72 hours, if left untreated
- Have been unsuccessful with or unable to take other oral medications for the prevention of migraine

Medications, drugs, and devices have to be approved for use by the Therapeutic Goods Administration (TGA). Rimegepant is an experimental treatment. This means that it is not an approved treatment for migraine in Australia.

Rimegepant has been approved for the treatment of acute migraine in adults, in the United States by the US Food & Drug Administration and in Europe by the European Medicines Agency. As of February 2022, approximately 5,800 individuals have used rimegepant while participating in a clinical study.

Information learned from the study may help people who suffer migraine headaches and have been unsuccessful with or unable to take other oral medications for the prevention of migraine.

This research is being conducted by Biohaven Pharmaceuticals Inc.

## 3 What does participation in this research involve?

If you decide to take part in this research project, you must sign your name at the end of this form and date it. Once you have signed and dated this form you will be considered enrolled as a participant for this study.

Your participation in this study will last about 30 weeks and will include about 10 study visits to the study center. Below is a breakdown of the different phases of the study.

- The **Observational Phase** is the first part of the study and is scheduled to last for a total of 4 weeks (2 site visits).
- The **Double-Blind Study Treatment Phase** is the second part of the study and is scheduled to last for a total of 12 weeks (5 site visits).
- The **Open-Label Extension Phase** is the third part of the study and is scheduled to last for a total of 12 weeks (2 site visits).
- The **Follow-up Phase** is the third part of the study and is the last 2 weeks of the study (1 site visit).

**Brief Description of the Study**

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). This study will test the effectiveness of rimegepant compared to placebo for the prevention of migraine headaches. A placebo is a

medication with no active ingredients. It looks like the real thing but is not. You will have a 1 in 2 chance of receiving Rimegepant if you decide to participate in this study.

This is also a double-blind study, which means that you, the participant, and the study doctor will not know which treatment the participant (you) is receiving. However, in certain circumstances (like an emergency) the study doctor can find out which treatment the participant (you) is receiving. This study also includes an open-label treatment phase, where you will receive Rimegepant. There is no placebo during the open-label treatment phase of this study.

***Enrolment:*** This study will use competitive enrolment. This means that when a target number of participants begin the Double-Blind Study Treatment Phase, all further enrolment 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 participants 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.

***Prohibited Medications:*** A number of prescription and over-the-counter medications are prohibited during your participation in this clinical trial. These medications are not allowed due to concerns over the potential for an unfavourable interaction with study medication (rimegepant). These unfavourable interactions may result in an increased risk for a safety event (such as nausea or another, more serious event) or a reduction in the potential benefits of taking rimegepant for the preventive treatment of migraine. In addition, some medications and medical devices are prohibited during your participation in the clinical trial because their use could compromise the ability to properly interpret study results. Some examples of prohibited medications during the clinical trial include, but are not limited to:

- Other oral migraine-preventive medications (such as: amitriptyline, atenolol, atogepant, bisoprolol, butterbur, candesartan, clonidine, desvenlafaxine and more)
- Injectable medicines for the preventive treatment of migraine (including eptinezumab, erenumab, femanezumab, galcanezumab, and Botox)
- The use of other investigational therapies (drugs not yet approved by government agencies)
- Medical devices for the preventive treatment of migraine (including nerve blocks, occipital nerve stimulators, transcranial magnetic stimulation, etc.)

*Of note, if you are using any of the above ORAL migraine-preventive medications for reasons other than the preventive treatment of migraine AND there has been no change in dose (strength or frequency of dosing) for at least 3-months prior to the Screening Visit, you may still be eligible for enrollment into the trial while continuing that medication. Any of the medications listed above are permitted during the study if administered as a topical agent or eye drops and if applied in a routinely accepted manner.*

It is important for you to speak with your study doctor about all medications (prescribed, over-the-counter, vitamins, herbals, etc.) you are taking or have taken in the 6-months prior to entering into this study.

Before you discontinue any of your medications, it is important that you consult with the clinician who is prescribing the medication to you and your regular healthcare provider(s).

**<u>The Observational Phase (up to 4 weeks)</u>**

The Observational Phase will have two scheduled clinic visits: Screening and Pre-Randomization. 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 document. 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. The study doctor will ask you to sign and date a separate document authorising the release of your private medical records for review and collection in this study. This request will be completed to assist study staff with study eligibility criteria.
- You will be asked about your typical migraine symptoms, frequency, severity and how your migraine 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 will be measured.
- You will have blood samples collected (approximately 1 tablespoon or 20 mL) for laboratory tests.
    - You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected.
    - 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 (like 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. Counselling will be provided both before and after HIV/Hep C testing.
- 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.
    - Women who can become pregnant will need to undergo a urine pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able 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).In addition to this questionnaire about suicidality, which is reviewed on the day with a study doctor, participants are encouraged to report any such problems or symptoms to the study doctor at any time.
- You will be asked how you are feeling and if you had any important medical events recently.
- You will be given a medication paper diary to complete at home. You will be required to record any medications or supplements you currently 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. During the Observational Phase, the eDiary will alarm daily with reminders to complete the headache report. During the Observational 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 medication at this visit.
- This visit will take approximately two to three hours.

Pre-Randomization Visit:

- You will be asked about all medications and supplements you currently take or have taken since the Screening Visit. Study staff will review this list of medications with you.

- You will have blood samples collected (approximately 1 tablespoon or 20 mL) for laboratory tests
    - You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected.
    - Women who can become pregnant will need to undergo a pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able 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.
- Study staff will review use of all medications and supplements you currently are taking or have taken throughout the course of the study. You will be required to continue to record the use of any medication or supplements on the medication paper diary.
- You will review the daily eDiary response with study staff to ensure there are no errors.
- You will not receive study medication at this visit.
- This visit will take approximately one hour.

**The Double-Blind Study Treatment Phase (12 weeks)**

During the double-blind study treatment phase there are a total of five visits: (Baseline/randomization, 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 28 days after completion of the Screening Visit.

At the Baseline visit, eligible participants 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, use the eDiary to report when you experience 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 the study medication. The eDiary will provide you with reminders to take the study medication on your “scheduled dosing days”.
- Every day, the eDiary will alarm with reminders to complete the headache report and the Patient Global Assessment (PGA) to understand your current condition and ways your migraine condition affects you.
- Once every 7 days, the eDiary will alarm with a reminder to complete the Migraine Functional Impact Questionnaire (MFIQ) to help understand how migraine affects your day-to-day activities.
- You will continue to complete your medication paper diary if you are taking any medications or supplements for any reason. Please record any medication use other than study medication 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.

Baseline (Randomization) Visit:

The following tests and procedures will be performed:

- Review of any changes in your health since your last visit.
- Study staff will review use of all medications and supplements you currently are taking or have taken throughout the course of the study. You will be required to continue to record the use of any medication or supplements on the medication paper diary.
- A physical examination will be performed.
- Your vital signs and weight will be measured.
- Women who can become pregnant will be required to take a urine pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able 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 paper questionnaires:
    - Columbia-Suicide Severity Rating Scale to record any thoughts of suicide you may have had and any suicidal actions you may have taken.
    - Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities.
    - Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraine have on your quality of life between migraine attacks.
    - Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.
    - Headache Impact test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.
- The study doctor and study staff will ask you to complete the following electronic questionnaires within your eDiary each day, starting at the Baseline Visit:
    - Patient Global Assessment (PGA) to help understand your current condition and ways your migraine condition affects you.
    - Migraine Functional Impact Questionnaire (MFIQ) to help understand how migraine 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 medication (2 blister packs) and will tell you how and when to take the study medication. You will be provided dosing instructions.
- **You will take your first dose of study medication while you are at the clinic for the Baseline Visit.**
- This visit will take approximately two hours**.**

Week 2, Week 4, and Week 8 Visits:

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.
- Study staff will review use of all medications and supplements you currently are taking or have taken throughout the course of the study. You will be required to continue to complete your medication paper dairy if you are taking any medications or supplements for any reason other than the study medication.
- A physical examination will be performed.
- Your vital signs and weight will be measured.
- Women who can get pregnant will be required to undergo a urine pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able to participate in this study.
- You will be asked about how you have been feeling since your last visit.
- At every visit, you must bring:
    - Your eDiary for review of completeness.
    - Your Medication Paper Diaries for review of completeness.
    - Your Study drug (used and unused blister packs).
- Any used and unused blister packs of study medication will be collected.
- Additional study medication will be dispensed.
- These visits will take approximately one hour.

At Week 4, the following tests and procedures will be performed in addition to those mentioned above:

- Blood samples will be collected for laboratory tests (approximately 1 tablespoons or 20 mL). You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected. You will be asked to complete the Columbia-Suicide Severity Rating Scale paper questionnaire to record any thoughts about suicide you may have had and any suicidal actions you may have taken.

At Weeks 4 and 8, in addition to the procedures mentioned above, you will be asked to complete the following paper questionnaires:

- Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities.
- Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraine have on your quality of life between migraine attacks.
- Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.
- Headache Impact Test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.

Week 12 Visit:

The following tests and procedures will be performed at Week 12 or if you end your participation early for any reason:

- A physical examination will be performed.
- Your vital signs and weight will be measured.
- You will have blood samples collected (approximately 1 tablespoons or 20 mL). You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected.
- Women who can get pregnant will be required to undergo a urine 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.
- Study staff will review the medications and supplements you currently are taking or have taken throughout the course of the study. You will be required continue to complete your medication paper diary if you are taking any medications or supplements for any reason other than the study medication.
- Your eDiary will be reviewed and returned.
- You will return any used and unused blister packs of study medication.
- You will be asked to complete the following paper questionnaires during this visit:
    - Columbia-Suicide Severity Rating Scale to record any thoughts about suicide you may have had and any suicidal actions you may have taken.
    - Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities.
    - Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraine have on your quality of life between migraine attacks.
    - Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.
    - Headache Impact Test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.
- This visit will take approximately one hour.

**The Open-Label Extension Phase (12 weeks)**

To qualify to participate in the Open-Label Extension Phase of the study, you will need to complete ALL of the visits and procedures of the Observational Phase and Double-Blind Study Treatment Phase. Furthermore, you will need to be compliant with taking your study medication during the Double-Blind Study Treatment Phase to qualify. During the Open-Label Extension Phase there are a total of two visits (Week 14 and Week 24/EOT).

During the Open-Label Extension Phase you will continue to take one table of the study drug (Rimegepant 75 mg ODT) every other calendar day, even if you do not have a migraine that day. Treatment with Rimegepant will being two calendar days after the final scheduled dosing day for the Double-Blind Study Treatment Phase, to maintain the every-other-day dosing schedule during this phase. During this phase, you, the study doctor, study staff and the

Sponsor will know the study drug and the dose that you are given. There is no placebo during this part of the study.

When you experience a migraine or taking any other medication or supplements, you should use the medication paper diary. 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.

Week 14 Visit:
The following tests and procedures will be performed:

- A targeted physical examination will be performed.
- Your vital signs and weight will be measured.
- Blood samples will be collected for laboratory tests (approximately 1 tablespoons or 20 mL). You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected.
- Women who can get pregnant will be required to undergo a urine pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able 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 how you are feeling and if you had any important medical events since your last visit.
- Study staff will review the medications and supplements you currently are taking or have taken throughout the course of the study. You will be required continue to complete your medication paper diary if you are taking any medications or supplements for any reason other than the study medication.
- Your paper diary will be reviewed and returned.
- You will return the used and unused blister packs of study medication.
- You will be asked to complete the following paper questionnaires during this visit:
    - Columbia-Suicide Severity Rating Scale to record any thoughts about suicide you may have had and any suicidal actions you may have taken.
    - Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.
    - Patient Global Assessment (PGA) to help understand your current condition and ways your migraine condition affects you.
- This visit will take approximately one hour.

Week 24 or Open-Label Extension End of Study Treatment Visit:
The following tests and procedures will be performed at Week 24 or if you end your participation early in the open-label extension phase for any reason:

- A full physical examination will be performed.
- Your vital signs and weight will be measured.
- Blood samples will be collected for laboratory tests (approximately 1 tablespoons or 20 mL). You should not eat at least 8 hours prior to these blood tests. Refreshments will be provided after blood samples are collected.
- Women who can get pregnant will be required to undergo a urine pregnancy test. The result of the pregnancy test must show that the woman is not pregnant to be able 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 how you are feeling and if you had any important medical events since your last visit.
- Study staff will review the medications and supplements you currently are taking or have taken throughout the course of the study. You will be required continue to complete your

medication paper diary if you are taking any medications or supplements for any reason other than the study medication.
- Your paper diary will be reviewed and returned.
- You will return the used and unused blister packs of study medication.
- You will be asked to complete the following paper questionnaires during this visit:
    - Columbia-Suicide Severity Rating Scale to record any thoughts about suicide you may have had and any suicidal actions you may have taken.
    - Migraine-Specific Quality-of-Life Questionnaire (MSQ) to help understand the effects of migraine headache on your daily activities.
    - Migraine Interictal Burden Scale (MIBS) to assess the impact recurrent migraine have on your quality of life between migraine attacks.
    - Work Productivity and Activity Impairment (WPAI) Migraine to help understand about migraine and your ability to work and perform regular activities.
    - Headache Impact test (HIT-6) to assess the severity of your migraine headaches and any corresponding change in your health status over time.
    - Patient Global Assessment (PGA) to help understand your current condition and ways your migraine condition affects you.
- This visit will take approximately one hour.

**The Follow-up Visit (2 weeks)**
- Review of any changes in your health since your last visit.
- A targeted physical examination will be performed.
- Your vital signs and weight will be measured.
- Women who can become pregnant will need to undergo a urine pregnancy test.
- You will be asked how you have been feeling since your last visit.
- The completed medication paper diary will be collected and reviewed.
- .
- This visit will take approximately half an hour.

**About the Study Treatments**

The study medications are rimegepant or a matching placebo. Rimegepant is a disintegrating tablet (a tablet that is taken orally 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 matching placebo (inactive substance). You will have a 50% chance (1 in 2) of receiving rimegepant and a 50% chance (1 in 2) of receiving a matching placebo. This is a double-blind study, which means neither you nor your study doctor (Investigator) will know to which of the study medication 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 medication every other calendar day, even if you don't have a migraine. These are considered "scheduled dosing days". You cannot take the study medication on the days between the "scheduled dosing days" (that is on "non-scheduled dosing days"). You are not allowed to take the study medication to treat an acute migraine. Study medication should be taken for the first time at the **Baseline Visit**.

During the **Open-Label Extension Phase**, you will be required to take 1 tablet of study medication every other calendar day. These are considered "scheduled dosing days". You cannot take study drug on the days between scheduled dosing days ("non-scheduled dosing days"). Open-label study drug should begin two calendar days after the final scheduled dosing day for the double-blind study drug, to maintain the every-other-day dosing schedule throughout the course of the study. You are not allowed to take study drug to treat an acute migraine. You will have a 100% chance of receiving rimegepant. This is known as open-label, which means

both you and your study doctor (Investigator) will know active study drug (rimegepant) will be assigned, even if you don't have a migraine.

Treatment after the study:
Because this is a research study, the study medication will be given to you only during this study and not after the study is over. This study medication will not be available on prescription for preventing migraine.

**Costs**
There are no additional costs associated with participating in this research project. The study medication, tests and medical care required as part of the research project will be provided to you free of charge.

You will not be compensated for participating in this research project.

If you have any questions regarding your compensation for participation, please contact the study staff using the details provided within this document.

**Informing your local doctor**
It is desirable that your local doctor be advised of the decision to participate in this research project. If you have a local doctor, the study investigator or study staff will inform them of your participation in this research project.

## 4 What do I have to do?

**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 medication as instructed by the study doctor and study staff.
- Store the study medication as instructed by the study doctor and study staff.
- Return all unused study medication blister packs to the study staff. Bring the unused study medication blister packs 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.

**The Investigator 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 fail 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 cancelled; or
- If for administrative reasons, including competitive enrolment where the target number of participants have 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.

## 5 Other relevant information about the research project

About 1000 participants will participate in this study and about 600 participants will receive rimegepant or a matching placebo.

This study is being conducted in 16 countries at about 125 centers. Each center is expected to enrol about 5 participants. At this center about 5 participants are expected to be enrolled.

## 6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide that you can take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide that you can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether you can take part or not take part, or take part and then be withdrawn, will not affect your routine treatment, or your relationship with those treating you, or your relationship with Genesis Research Services.

## 7 What are the alternatives to participation?

You do not have to take part in this research project to receive preventive treatment. Potential options that may be appropriate for you include the following injectable medications specifically approved for the preventive treatment of migraine:

- eptinezumab (“Vyepti”)
- erenumab (brand name “Aimovig”)
- fremanezumab (“Ajovy”)
- galcanezumab (“Emgality”)

In addition, the following medications, while not specifically indicated or approved for the preventive treatment of migraine, have demonstrated the potential to reduce the number of migraine attacks an individual experiences on a monthly basis. Please note, this is an incomplete list of alternative preventive treatment options. Please speak with your Investigator and personal doctor about what treatment options might be best for you.

- amitriptyline
- venlafaxine
- atenolol, metoprolol
- candesartan, lisinopril
- vitamin B12, magnesium citrate

- Please note, the above represent an incomplete list of alternative preventive treatment options.

Your study doctor will discuss these options with you before you decide whether or not you will take part in this research project.

## 8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include relief from migraine. Information learned from this study may help other people in the future.

## 9 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or

you are worried about them, talk with the study doctor. The study doctor will also be looking out for these side effects. There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop your treatment. The study doctor will discuss the best way of managing any side effects with you.

**Risks associated with the experimental treatment (rimegepant)**

Rimegepant is an approved treatment for preventive treatment of migraine in adults in the United States and Europe (not Australia). As of 26-August-2022, approximately 6,036 people have received rimegepant at any dose while participating in migraine or trigeminal neuralgia studies.

The most common adverse effect possibly related to the use of rimegepant for the prevention of migraine is nausea (1.4% or 14 in 1000). 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 (lower than 1% or lower than 1 in 100).

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** summarises the most common side effects by body system and rate of occurrence (minimum 2% or 2 in 100), and
- **Table 2** summarises the most common “severe” side effects by body system and rate of occurrence (minimum of more than 2 participants).

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

**Table 1: Most Common Side Effects and Rates of Occurrence in 2,471 Adults Receiving Multiple Doses of Rimegepant as Participants in Clinical Studies (minimum, 2% or 2 in 100)**

| Side Effects | Number of Participants (%) |
|---|---|
| Upper respiratory tract infection (a cold) | 209 (8.5% or ~8-9 in 100) |
| Nasopharyngitis (cold-like symptoms) | 170 (6.9% or ~6-7 in 100) |
| Sinusitis (swelling of the nasal sinuses) | 114 (4.6% or ~4-5 in 100) |
| Urinary tract infection | 96 (3.9% or ~3-4 in 100) |
| Influenza (flu) | 84 (3.4% or ~3 in 100) |
| Bronchitis (swelling in the large airways in the lungs) | 63 (2.5% or ~2-3 in 100) |
| Nausea | 67 (2.7% or ~2-3 in 100) |
| Back pain | 86 (3.5% or ~3-4 in 100) |
| Arthralgia (joint pain) | 55 (2.2% or ~2 in 100) |
| Dizziness | 53 (2.1% or ~2 in 100) |

**Table 2: Most Common Severe Side Effects and Rates of Occurrence in 2,471 Adults Receiving Multiple Doses of Rimegepant as Participants in Clinical Studies (minimum, more than 2 participants)**

| Side Effect | Number of Participants (%) |
|---|---|
| Migraine | 4 (0.2% or 2 in 1000) |
| Anemia (low red blood cell count) | 3 (0.1% or 1 in 1000) |
| Influenza (flu) | 3 (0.1% or 1 in 1000) |
| Back pain | 3 (0.1% or 1 in 1000) |
| Osteoarthritis (pain and swelling due to degeneration of a joint[s]) | 3 (0.1% or 1 in 1000) |
| Nephrolithiasis (kidney stone) | 3 (0.1% or 1 in 1000) |
| Asthma | 3 (0.1% or 1 in 1000) |

***Note:*** *A "severe" side effect 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 medication, there is a small but real risk of allergic reactions that can be life-threatening or fatal. Severe reactions with any medication can include difficulty breathing and 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 heartbeat
- Sweating

**If you have an allergic reaction, call 000 immediately for emergency medical care.**

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 foetuses 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 the 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.
- Fasting prior to blood tests: You have been asked to not eat for at least 8 hours prior to your blood tests, which may be inconvenient or cause discomfort like the feeling of hunger. Your tests will be scheduled for early in the morning, ensuring that most of the fasting will be overnight. Refreshments will be provided after blood samples are collected to alleviate any discomfort.
- 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 call the study doctor at the telephone number listed at the end of this form. If you feel in crisis, you can call 000 and/or Lifeline Australia at 13 11 14 for support 24 hours a day.

- Placebo: If you receive the placebo (the inactive substance) as part of this study, your symptoms may not improve.

**Unforeseen Risks**

Although rimegepant is approved in the United States by the US Food and Drug Administration and in Europe by the European Medicines Agency (EMA) for the acute and preventive treatment of migraine attacks in adults, the dosing of rimegepant more than 18 days per month (28-days) is investigational and is not permitted in this or other ongoing trials. 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 medications 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 the study doctor at the phone number listed at the end 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 foetus 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 research project, you will be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that collects information about you. The eDairy is a hand-held electronic device that will be provided to you along with instructions for use. While using these, information about you may be collected and shared with the study team or with contracted partners. This may include personal health information, location, call logs, or text message history. The Sponsor of the trial and their contracted partners will 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 trial.

To ensure confidentiality and security of your e-diary and data, all transmissions of data collected from the e-diary to the database is done using an “encrypted” format. Encryption is a way of scrambling data so that only authorised parties can understand the information and it cannot be changed in anyway.

Personal data collected in the e-diary is anonymised, which means, replacing any information which could be used to identify an individual with a value which does not allow the individual to be directly identified. Participants of this study are identified using an identifier code, and it is not possible to identify the person by the data collected on the device.

## 10 What will happen to the participant’s test samples?

Samples are any fluid (e.g., blood, urine) collected from you in this study. The sponsor will use the samples collected from you for the purposes of this study.

To protect your privacy, your samples will be labeled with your study number. The scientists doing the research will not know your identity.

Samples of your blood obtained for the purpose of this research project will be transferred to a central laboratory for testing and analysis. Samples will not be stored.

The proposed blood tests include a screening test for HIV (also called the 'AIDS' virus) and Hepatitis. This is because the study doctors need to know if the participants are eligible to take part in this study. Counselling will be provided both before and after HIV/Hep C testing.

## 11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue to participate in this research project. If you decide to withdraw, the study doctor will make arrangements for your regular health care to continue. If you decide that you can continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in your best interests to be withdrawn from the research project. If this happens, the doctor will explain the reasons and arrange for your regular health care to continue.

## 12 Can I have other treatments during this research project?

Whilst participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during your participation in the research project. The study doctor should also explain to you which treatments or medications need to be stopped while you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

**Contraception Requirements**

Taking the study drug may involve risks to a pregnant woman, an embryo, foetus (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 end of this form).

Females (sex designation at birth):

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 and 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 participating in this study (starting at the time of written consent) and for **60 days** after taking the last dose of the study medication.

In this study, recognized highly effective methods of contraception include approved contraception pills, intrauterine devices (IUDs), and prior history of vasectomy (in males), etc. Other acceptable methods of contraception include barrier methods such as male or female condoms, and diaphragm.

The study doctor or study staff will discuss these with you.

If you become pregnant while you are participating in this study or within 60 days after you have stopped taking the study medication, tell the study doctor or study staff immediately. The study medication will be stopped and your participation in this study will be ended. The study staff will also collect information about the pregnancy, its outcome, and the health of the child after birth
If you become pregnant within 60 days after you have stopped taking the study medication, the study doctor may ask to review your 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 pregnancy and the baby with the study sponsor to help understand the effects, if any, that the study medication may have on the pregnancy and the child.

Males (sex designation at birth):
To reduce the risk of pregnancy, all 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 contraception (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 contraception are provided above (*See Females [sex designation at birth*]). Notably, vasectomy is considered as one highly effective method of contraception, and therefore, one additional form of contraception is required throughout the course of the study.

The study doctor or study staff will discuss these 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 medication, tell your study doctor or study staff promptly. 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 medication may have on the pregnancy and the child.

If you are a male (sex designation at birth), you must not donate sperm until 90 days following the last dose of study medication.

## 13 What if I withdraw from this research project?

You do not have to be in this study to receive treatment for your migraine.
Other options that may be appropriate in discussion with your treating doctor are:

- aspirin
- acetaminophen
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen
- triptans
- combination pain relievers

Some of these drugs are approved by the Therapeutic Goods Administration (TGA) 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.

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

If you stop the study early, you will be asked to return to the study doctor to have final tests done.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project. If you decide to stop the study early, you agree not to limit the sponsor's use of your study information.

If you stop the study early and withdraw your consent to participate in the trial, your blood samples which have NOT been tested at the time that you withdraw consent will be destroyed so that they cannot be analysed any more.

## 14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The study drug being shown not to be effective
- The study drug being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

Your study doctor also has the right to take you out of the study at any time, or the sponsor may direct your doctor to take you out of the study, if:

- It is in your best medical interest to stop your participation
- You do not follow instructions
- The study is cancelled

## 15 What happens when the research project ends?

After you complete the study (or if you stop early), your study doctor may contact you again. If your study doctor is unable to contact you, he/she may contact a member of your family or ask one or more of the doctors you see regularly to find out about your health status. By signing this form, you agree that this information can be added to your study record.

# Part 2 How is the research project being conducted?

## 16 What will happen to information about me?

**Permission for access to records and confidentiality**

The study doctor and his/her staff will collect personal information about you in your medical records. They will enter this information on to study forms for the Sponsor. These will include your date of birth and a unique number assigned to you. Only information relevant to the study will be collected on the study forms. All information collected about you during the study will be kept confidential.

Your medical records may be directly accessed by the study doctor, staff of the study doctor or institution involved in the study and representatives of the Sponsor, and health authorities for the conduct of the study and for verification of clinical trial procedures and/or data. Your study records may be accessed by the Bellberry Human Research Ethics Committee.

The Sponsor will use the de-identified information provided by you and obtained in this study to generate scientific information about its products, to conduct clinical trials, verify and audit such studies, to conduct post marketing surveillance and retrospective studies, undertake other surveys and for the other purposes stated in this Participant Information Sheet and Informed Consent Form.

Your de-identified information (i.e., information that does not disclose your identity) may also be used by or disclosed to third party contractors, Government agencies and related companies of the Sponsor (including those based outside of Australia) for research, reporting or statistical purposes.

Study information will be sent to other countries for entry into a computer and review for the purposes of the trial. Only trained employees of the Sponsor and its related companies will view and evaluate this information for the purposes of the study. All of these people will keep the information confidential.

The information collected about you for this trial will be stored securely and retained for 15 years or until no longer required by the sponsor, as per applicable regulations.

Your name will not appear in study reports or publications about the study drug.

As the study is for research purposes, it is hoped that valuable and important information will be obtained from the results. This could include new drugs, treatments, and technologies. All information and intellectual property obtained through the study, or generated as a result of the study, will be the property of the Sponsor.

To obtain access to your personal information or correction of this information contact the study doctor.

If you do not want to provide the information that the study doctor asks for, you may not participate in this study. By signing this form, you are giving permission for your personal information to be stored and used as explained in this Participant Information Sheet and Informed Consent Form.

Your General Practitioner (GP) and/or specialist will be notified of your participation in this study and of any clinically relevant information.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov in accordance with U.S. Law (Study identifier is NCT05518123). This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time. This is also in accordance with the Australian *National Statement on Ethical Conduct in Human Research* (2007).

Participants should note that, some data from your participation in this study will be sent overseas or shared with persons outside Australia; the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. In the case of data that identifies you, or from which your identity may be ascertained, an entity subject to Australian privacy laws that has collected your information must take reasonable steps to ensure that an overseas recipient handles the information in accordance with any relevant Australian privacy principle (unless an exemption applies). If you have any questions about this direct them to the Principal Investigator

## 17 Complaints and Compensation

**Compensation for Injury**

If you become ill or suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

- The pharmaceutical industry has set up a compensation process, with which the Sponsor of this research project, Biohaven Pharmaceuticals, Inc., has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request.

- You may be able to seek compensation through the courts.

This statement does not limit your legal rights.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

## 18 Who is organising and funding the research?

This research project is being conducted by Biohaven Pharmaceuticals, Inc. Your study doctor is being paid by Biohaven Pharmaceuticals, Inc. to conduct this study.

The Sponsor may benefit financially from this research project if, for example, the study assists them to obtain approval for rimegepant.

By taking part in this research project, you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to the Sponsor, who may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to the Sponsor.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the Sponsor, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Genesis Research Services will receive a payment from the Sponsor for undertaking this research study.

Neither Dr Marc Russo nor Genesis Research Services have any affiliations (financial or otherwise) which are considered to be a conflict of interest to conducting this study.

No member of the research team will receive a personal financial benefit from your involvement in this research study (other than their ordinary wages).

## 19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent committee responsible for ensuring the rights and wellbeing of research participants are protected. This research project is reviewed by Bellberry Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

## 20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

During the study, if you want any further information concerning this project or experience any medical problems which may be related to your involvement in the project (for example, any side effects), 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 participant;
- 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 on 49851860**

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

**Clinical contact person**

| | |
|---|---|
| Name | Richelle Powell |
| Position | Clinical Trial Coordinator |
| Telephone | 02 4985 1860 |
| Email | richelle@genesisresearchservices.com |

Please reference the following number when contacting the Clinical Contact Person: **BHV3000-407.**

For matters relating to research at the site at which the participant is participating, the details of the local site complaints person are:

**Complaints contact person**

| | |
|---|---|
| Name | Emily Allard |
| Position | Research Manager |
| Telephone | 02 4985 1860 |
| Email | emily@genesisresearchservices.com |

Please reference the following number when contacting the Complaints Contact Person: **BHV3000-407.**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

| | |
|---|---|
| Reviewing HREC name | Bellberry |
| HREC Executive Officer | Peter Wigley |
| Telephone | 08 8361 222 |
| Email | peterwigley@bellberry.com |

**Local HREC Office contact (Single Site -Research Governance Officer)**

| | |
|---|---|
| Name | Emily Allard |
| Position | Research Manager |
| Telephone | 02 4985 1860 |
| Email | emily@genesisresearchservices.com |

Please reference the following number when contacting the HREC Office: **BHV3000-407.**

# Consent Form - *Adult providing own consent*

| | |
|---|---|
| **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 |
| **Short Title** | Rimegepant for Prevention of Migraine |
| **Protocol Number** | BHV3000-407 |
| **Project Sponsor** | Biohaven Pharmaceuticals, Inc. |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Marc Russo MBBS DA (UK) FANZCA, FFPMFANZCA |
| **Associate Investigator(s)** | Dr Cillian Suiter, Dr Ulrich Liedvogel |
| **Location** | 220 Denison Street Broadmeadow NSW |

**Declaration by Person Responsible**

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals, or laboratories outside this hospital to release information to Genesis Research Services concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I understand that my involvement in this study may not be of any direct benefit to me.

I have been given the opportunity to have a member of my family or another person present while the study is explained to me.

I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.

I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event and I consent to this access.

I am 18 years of age or over.

I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

I declare that all my questions have been answered to my satisfaction.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

# Form for Withdrawal of Participation - *Adult providing own consent*

| | |
|---|---|
| **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 |
| **Short Title** | Rimegepant for Prevention of Migraine |
| **Protocol Number** | BHV3000-407 |
| **Project Sponsor** | Biohaven Pharmaceuticals, Inc. |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Marc Russo<br>MBBS DA (UK) FANZCA, FFPMFANZCA |
| **Associate Investigator(s)** | Dr Cillian Suiter, Dr Ulrich Liedvogel |
| **Location** | 220 Denison Street Broadmeadow, NSW |

**Declaration by Person Responsible**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Genesis Research Services

Name of Participant (please print) _____

Signature _____ Date _____

*In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project, and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.