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Patient Information Sheet and Consent Form

Patient Initials:_____ Patient number:_____

Main Study Title:	Randomized, Double-Blind, Placebo-Controlled, Multiple-Attack Study with an Open-Label Extension to Evaluate the Efficacy, Safety, Tolerability, and the Consistency of Effect of Atogepant for the Acute Treatment of Migraine (ECLIPSE)
Protocol Number:	M24-305
EU CT:	2023-506029-12-00
Sponsor:	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland
Local Representative of Sponsor	AbbVie Ltd, AbbVie House, Vanwall Road, Maidenhead, Berkshire, SL6 4UB
CONTACT INFORMATION:	
Study Doctor:	Dr Daniel Lashley
Address:	Re:Cognition Health Bristol Unit 240, Phase 200 Aztec west Bristol BS32 4SY
Telephone:	01174623600 Option 1 (8.30am – 5.30pm Mon to Fri)
After Hours Telephone:	PI mobile number: 07701087629 If you call is not answered, please text this number and Dr Lashley will get back to you as soon as he can
Ethics Committee or other contact information, if applicable	North East - Tyne & Wear South REC Health Research Authority, 2nd Floor 2 Redman Place London E201JQ United Kingdom

PART 1

Invitation to take part

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and talk to other friends, relatives or your GP about this study if you wish. A member of our team will go through this Patient Information Sheet with you and answer any questions you have.

- **Part 1** tells you the purpose of this study and what will happen to you if you take part; and
- **Part 2** gives you more detailed information about how this study will be conducted.

There is a consent form at the end of Part 2 that you will need to read and fill out if you would like to take part in the study. If there is anything that is not clear or if you would like more information, please ask.

The names of the sponsor for this study and its local representative are listed in the table above, and they are together referred to as "AbbVie" in this consent.

What is the purpose of this study & why have I been invited?

The purpose of this study is to evaluate the efficacy, safety, and tolerability of a single dose of atogepant compared to placebo for the acute treatment of a single migraine attack, and evaluate the efficacy, safety, and tolerability of atogepant for the acute treatment of multiple migraine attacks.

What is the drug being tested?

You have been asked to participate in a research study of a study drug called atogepant. The study drug has been approved by regulatory authorities in multiple countries for prevention of migraine but is not approved for the acute treatment of migraine. Therefore, the use of the study drug is investigational (experimental) for the purposes of this study.

It is planned that the study will be conducted in approximately 160 centres in Europe and Asia-Pacific. Approximately 1,300 adults will be enrolled to receive treatment.

In this study, atogepant or placebo will often be described as the 'study drug(s)'.
During the first period of the study, the double-blind treatment period (see Study Design section below), you will receive both atogepant and placebo to treat 4 qualifying migraine attacks. Placebo tablets look exactly like atogepant tablets and will be used to ensure that you, or the study staff, cannot guess what you are actually taking. A placebo is not a drug and it is not expected to have any chemical effects on your body. It is not designed to treat any disease or illness. You will be randomly assigned to a treatment sequence where you will receive both placebo and atogepant; for each attack you will receive either placebo or atogepant. During this double-blind treatment period, you will not be told or know whether you are taking atogepant or placebo when treating a migraine attack. However, this information is available should the study doctor decide it is medically necessary.

During the second period of the study, the open-label treatment period (see Study Design section below), you will receive atogepant only.

In order to take part in this study you must meet certain requirements, including:

- You are between 18 to 75 years old.
- You had your first migraine before age 50.
- You have experienced migraines for at least 1 year.
- On average, you experience 2 to 8 migraine attacks per month.

This is not a complete list of requirements. The study doctor will review all requirements with you to determine if you meet the study requirements and can enter the study.

Do I have to take part?

No. It is totally up to you to decide whether or not to take part. We will discuss this study and the optional research with you and if you agree to take part, we will ask you to read and sign a consent form to show that you have agreed to take part in this. You will be given a copy of this Patient Information Sheet and a signed copy of the consent form to keep.

What do I have to do?

Taking part in a research study can be an inconvenience to your daily life. In order for this study to be successful and to collect accurate information about how atogepant works in migraine, it is important that you follow the following responsibilities as a study patient:

- Come to your study visits as scheduled.
- Provide truthful, accurate and complete information about your past and current medical conditions.
- Provide your study doctor and study staff with a complete list of all the medication you are taking.
- Fill out your dosing sheet, questionnaires and/or diary completely and honestly
- Tell the study staff of any side effects or health problems you are having even if you don't think they are important or related to study drug.
- Tell the study staff if you wish to stop taking part in this study. You should come back for the end of study visit and return all study supplies.
- Tell the study staff if you are invited to receive a new vaccine (e.g. for COVID-19).
- **IMPORTANT:** Please do not change any of your medicines or take any new medication without checking with your study doctor. Certain medications may result in an increase in side effects with the study drug.

You will be given a "**Subject Information Card**" describing that you are participating in a clinical study. This will contain your study doctor's contact details and inform other medical personnel that you are participating in a research study. Remember to carry this card with you at all times whilst you are on this study. You should show this card to anyone who gives you medical treatment.

If you feel that this study would take up too much of your time or you do not think you can meet the responsibilities highlighted in this section, you should not agree to be in this study. Please let your doctor know so they can discuss alternative treatments with you.

Subject Responsibilities:

In order for this study to provide good information about how the study drug(s) work in subjects with your condition, you will be expected to do, or avoid, the following:

DO:

- attend all study visits
- follow the directions of the study doctor and study team
- tell the study doctor if you are feeling bad or worse than before and/or if you have thoughts of suicide
- carry your subject ID card with you as long as you are in the study and show it to any medical staff that may be involved in your healthcare
- fill out your subject paper cards, and eDiary completely and honestly and bring them with you to each study visit
- ensure your eDiary device is fully charged and keep your eDiary device with you every day
- you should use acceptable forms of contraception during sexual intercourse throughout your participation in the study.
- tell the study doctor or study team if you believe you might be pregnant or may have gotten your partner pregnant.
- take your study drug as directed by the study doctor and keep your study drug with you at all times and
- take study drug with or without food

- bring back all study drug packaging, including unused study drug and empty blister cards, to each visit

DON'T:

- do not start taking any new medications, including prescribed medications from other doctors, non-prescription medications or alternative treatments/supplements such as St. John's Wort without speaking to your study doctor first.
- do not take part in other research study at the same time as participating in this one
- do not give the study drugs to others
- do not consume grapefruit or grapefruit juice

Dosing Instructions – Double-Blind Treatment Period:

Atogepant or matching placebo tablet (from your Double-Blind Treatment Period blister card)

Take one single tablet of the study drug that your study doctor has prescribed at the start of your qualifying migraine attack, with or without food (avoiding grapefruits or grapefruit juice). The study staff will explain what a qualifying migraine attack is. Study drug tablets should be taken in the pre-defined order as shown on the blister card packaging.

Dosing Instructions – Open-Label Treatment Period:

Atogepant (from your Open-Label Treatment Period blister card)

Take one single tablet of the study drug that your study doctor has prescribed at the start of your qualifying migraine attack, with or without food (avoiding grapefruits or grapefruit juice). The study staff will explain what a qualifying migraine attack is.

What will happen to me if I take part?

The study duration will last approximately 7 months. There will be 6 in-person visits where you will have to go to the study site and 3 telephone visits where the study team will phone you. You will be required to complete information in a handheld electronic device, called an eDiary, throughout the study.

Screening Period:

The study will consist of a screening period of up to 5 weeks, where you will be asked to participate in study procedures (see Study Procedures and Appendix A below). The results from these procedures will determine if you are eligible to participate in this study.

Double-Blind Treatment Period (where nobody, neither the study doctor, their staff, nor you, will know which study drug you are taking for each migraine attack):

If you are eligible to participate in the study, you will enter a double-blind treatment period and will receive the study drug. You will be provided with the study drug in a blister card to treat 4 qualifying migraine attacks. One blister card will contain 4 tablets of study drug. Each qualifying migraine attack will be treated with a single dose of study drug, following the order specified on the blister card.

During the double-blind treatment period, that could last up to 16 weeks, you will be asked to participate in study procedures (see Study Procedures and Appendix A below) so that the study doctor can monitor your health.

After treating 4 qualifying migraine attacks, you will enter into the open-label treatment period that will continue until the end of the study at Week 24.

Open-Label Treatment Period (where you and the study doctor will know that you are taking atogepant):
After treating 4 qualifying migraine attacks during the double-blind treatment period, you may begin the open-label treatment period (up to Week 24). You will be provided with sufficient study drug of atogepant to treat qualifying migraine attacks. Each qualifying migraine attack will be treated with a single dose of atogepant. If you do not treat 4 qualifying migraine attacks by Week 16 during the double-blind treatment period, you will be discontinued from the study at Week 16 and will not participate in the open-label treatment period.

During the open-label treatment period, you will be asked to participate in study procedures (see Study During the open-label treatment period, you will be asked to participate in study procedures (see Study Procedures and Appendix A below) so that the study doctor can monitor your health.

Follow-Up Period:
When you complete or withdraw from the study, you will receive a phone call from the study staff to follow up on your health, 30 days after your last visit.

Study Procedures:

Please see Appendix A for a summary of the study activities and when they occur. You will undergo one or more of the study procedures described in this form at screening and throughout the study.

- Informed consent - you must read this information, ask your study doctor any questions and then sign to give your consent to start the study. You can withdraw your consent at any time without giving a reason.
- Personal Information – the study team will ask you for some personal information such as your name, date of birth, race, etc.
- Health and Medication Questions - you will be asked to answer questions about your health, your medical history, and the medications you have taken in the past or are currently taking. You will also be asked questions about tobacco, alcohol and drug use. If you are participating at a non-NHS site, you may have responded to generalised or study specific advertising, the study staff at these sites will have discussed your general medical history with you in an initial discussion to determine if you were eligible for any of the studies they are running. Once you have been identified as being potentially eligible and if you confirmed your interest to take part in this study, their staff may contact your GP to obtain further information about your medical history regarding your eligibility for this study.
- Physical Exam - a check doctors often do of your body to confirm your state of health.
- Vital Signs - check your blood pressure, count the number of heartbeats over time, count the number of times you breathe in and out over a period of time, take your temperature and measure your height and weight.
- Electrocardiogram - An electrocardiogram (also called an ECG) measures the electrical activity of the heart. Sticky patches will be placed on your arms, legs and chest to do this test and you may be asked to lay quietly for a few minutes.
- Blood Sampling – the study team will take some blood to do laboratory tests.
    - Some of your blood will be used to test for Hepatitis B and C which are communicable diseases (diseases that can be spread from one person to another).
    - You can ask the study doctor or study staff what your blood might/will be tested for.
    - The study doctor or study staff will tell you if the test results are clinically significant.
    - The amount of blood taken at each visit will be between approximately 17 to 18 mL (1.5 to 3.5 teaspoons), totalling approximately 49 mL throughout the study.
- Urine Testing – a urine sample will be taken to do laboratory tests.
    - Some of your urine will be tested for recreational or illicit drugs.
    - The study doctor or study staff will tell you if the drug test results are positive. The results of the drug test must be negative or explained by the use of some medication that you are taking in order for you to be in the study.

- Pregnancy Test – Test your blood or urine to see if you are pregnant. You will only have pregnancy testing if you are a woman and can have children. If you think you may be post-menopausal, you may have a follicle-stimulating hormone (FSH) blood test to confirm
    - The study doctor or study staff will tell you if the pregnancy test results are positive
    - You must have a negative pregnancy test in order to participate in the study.
- Pharmacokinetic (PK) testing - PK testing uses a blood sample to measure the amount of study drug in the body at different time points. This will be done with a Dried Blood Sample (DBS) collection at home where you will perform a simple finger prick test, to allow a drop of blood to rise to the skin surface and be collected. You will be asked to collect 2 DBS samples during the double-blind treatment period after treating your first qualifying migraine attack with study drug at home; one DBS sample 2 hours after taking your dose of study drug and one DBS sample anytime between 4 and 12 hours after taking your dose of study drug. The study staff will explain how to collect the samples and a practice collection will be performed at Visit 2 to ensure you understand the procedure. You will then receive instructions and all the materials to collect DBS samples at home.
- Electronic diary (eDiary) - you will receive a handheld electronic device to take home with you. This will be used to collect information regarding your migraine attacks as well as questionnaires about your quality of life, physical and mental health and the study drugs. When you experience a migraine headache, you will also need to answer questions in the eDiary to determine if you are having a qualifying migraine attack and if you should take the study drug. The study staff will show you how the eDiary works and how to use it. You will complete a training module on the eDiary at home prior to participation in the study. If you are eligible to participate in the study, the expectation is for all questions to be answered in the eDiary after each qualifying migraine attack. You will be reminded to bring the eDiary to every clinic visit.
- Columbia Suicide Severity Rating Scale (C-SSRS) - A few questions will be asked by a qualified member of the study site staff about any suicidal thoughts or behaviours.
- The study staff will provide you with subject paper cards to record side effects that you experience in between clinic visits. The study staff will give you instructions on how to use the subject paper cards. You will need to bring your completed subject paper cards to the study centre at each visit.
- Study Drug – The study staff will give you a supply of study drug and tell you how to take it. You will be asked to confirm that you are taking the study drug in the correct order as indicated on the blister card for each migraine attack. You will bring back all study drug packaging, including unused study drug and empty blister cards, to each visit.

Risks related to Study Procedures:

- Blood Sampling - Blood draws may cause pain, bleeding, bruising and/or discomfort. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn.
- Electrocardiogram - ECG: Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. To do the ECG, you will have pads placed on different parts of your body. There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.
- Questionnaires – Answering questions about your emotional and mental health could make you feel uncomfortable or upset. Please tell the study staff if you feel uncomfortable or upset.

What are the alternative treatments?

You do not have to take part in this research study to receive treatment for your condition. Your study doctor will review treatment options that are appropriate for you together with the potential risks and benefits of each treatment.

What are the possible side effects of treatment with atogepant?

Atogepant is a prescription medicine taken by mouth that is being developed to prevent and treat migraine attacks in adults. We will often call atogepant the "study drug" here. You may have side effects, problems with your health, or changes in the way you feel during this study after taking atogepant. These possible side effects were found by giving this medicine to animals (mice, rats, rabbits, and monkeys) and more than 3500 people before you.

Side effects seen in a different drug that is very similar to atogepant are also included below even though they have not been seen with atogepant.

Tell your study doctor about any side effects or changes in the way you feel, even if they are not listed here.

What side effects have been seen in people given atogepant?

These side effects are common, they may happen in more than 1 in 100 people:

- Nausea
- Constipation (trouble passing stool)
- Fatigue/somnolence (tiredness/feeling sleepy)
- Decreased appetite (not feeling hungry)
- Weight loss
- Allergic reactions [rash, pruritus (itching), urticaria (hives), facial oedema (swelling)]

These side effects have generally been mild to moderate in severity.

Other side effects with atogepant:

While in clinical trials, some people who took atogepant had elevations of transaminase (also known as AST and ALT), which are markers in blood tests that measure possible injury to the liver. These elevations had no symptoms, and the levels became normal when they stopped taking atogepant.

Other side effects with similar drugs (ubrogepant, rimegepant):

While in clinical trials, some people experienced dry mouth (feeling like less saliva in the mouth) with ubrogepant, and hypersensitivity reactions (allergic reactions) with rimegepant and ubrogepant.

You may have all, some, or none of the side effects listed here. We will do everything we can to protect your health and will watch you carefully for any negative effects from taking this medicine.

As you continue to read, please ask your study doctor any questions about the side effects we describe.

Allergic reactions

A drug allergy is a reaction your body has to a medicine. If you have a mild allergy to a drug, you may have hives, a rash, or a fever. However, at rare times you could have a life-threatening allergic reaction to a medicine.

Call emergency services right away if you have any of these symptoms of a life-threatening allergic reaction while you are at home or you could die:

- Swelling around your mouth, throat, tongue, lips, or eyes
- Trouble breathing
- A whistling sound while breathing
- Chest tightness
- Dizzy or light-headed (from a sudden drop in blood pressure)
- Heart beating very quickly
- Passing out
- Feeling a sense of doom

Please tell your study doctor if you have any of these symptoms after taking atogepant.

Reproductive risks for female participants

What do I need to know about sexual health, pregnancy, and breastfeeding while taking part in this study?

We do not yet know if atogepant is safe for pregnant women, unborn babies, babies, or children who are nursing. We also do not know if atogepant is found in human breast milk, or if it affects breast milk production.

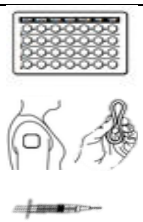
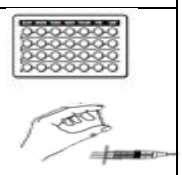
You cannot take part in this study if:

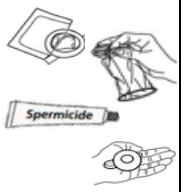
- You are pregnant or think you may be pregnant
- You and your partner are trying to get pregnant
- You are breastfeeding a child

If you are a woman who can get pregnant:

- Before you can take part in the study, you will get a pregnancy test to make sure you're not pregnant.
- You must agree to use birth control while in the study and for 30 days after the last time you take the study drug. Your study doctor will talk to you about your options and which method may be right for you.

The methods below are to prevent pregnancy in females in the study who take atogepant:

Method	What it includes	
Combined hormonal birth control with oestrogen and progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Birth control: • Taken by mouth (orally) • Placed in the vagina (intravaginal) • Placed on the skin (transdermal) • Taken as a shot (injectable)	
Hormonal birth control with only progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Birth control: • Taken by mouth (orally) • Placed in the body (implantable) • Taken as a shot (injectable)	
Bilateral tubal occlusion/ligation or Bilateral tubal occlusion/ligation by hysteroscopy with a hysterosalpingogram to confirm the procedure's success	A surgery that blocks or cuts the fallopian tubes to prevent the egg from being fertilized (also called having the "tubes tied")	
Intrauterine device (IUD) or Intrauterine hormone-releasing system (IUS)	A small device inserted into a woman's uterus to prevent pregnancy	
Vasectomized partner	An operation to make a man permanently unable to get a woman pregnant (as long as the partner verbally confirms the medical success of the surgery and is the sole sexual partner of the participant).	
Abstinence	Not having sex at all (as long as this is a part of the participant's long-term life choice). This doesn't include periodic abstinence (such as the calendar, ovulation, symptothermal, or post-ovulation methods) or the withdrawal method.	

If required per local practices, male or female condom with or without spermicide OR cap, diaphragm or sponge with spermicide should be used in addition to one of the birth control methods listed above (excluding true abstinence).		
Barrier	• Male or female condoms with or without spermicide • Cap, diaphragm, or sponge with spermicide (items placed in a woman's vagina that contain spermicide to block and kill sperm before it reaches an egg)	

Even if you use an effective method of birth control, you may still become pregnant. There may be risks to yourself while pregnant, to the baby, or the nursing infant that are currently not known. Once you are enrolled in the study, tell the study doctor or staff right away if you become pregnant, you think you might be pregnant, or you are trying to get pregnant.

If you become pregnant during the study, you will no longer get the study drug. Even if you are no longer taking the study drug, your study doctor will contact you to ask about your pregnancy and the pregnancy outcome.

Reproductive risks for male participants
Based on animal studies (including a fertility study) there is no effect of atogepant on male reproduction.

You should not get anyone pregnant while taking part in the study.

If you are male, to take part in this study, you **must** agree to:

- Use condoms even if you've had a vasectomy (an operation to make a man permanently unable to get a woman pregnant). You will have to use condoms from Visit 2/Randomization until 30 days after the last time you take the study drug.
- Not donate sperm while you are in the study and for 30 days after the last time you take the study drug. This is because the study drug might enter your sperm, and in turn, an unborn baby.

If your partner becomes pregnant while you are in this study, tell your study doctor right away. Even if you are no longer in the study or taking the study drug, your study doctor will contact you to ask about the pregnancy and the outcome. If a pregnancy happens, a form about the pregnancy outcome will be requested from your pregnant partner.

<u>Side effects from taking other medicines, food, or drinks</u>
Certain medicines, food, or drinks may change how atogepant works in your body and may increase the chance of side effects. Keep a list of medicines you take to show to your doctor, healthcare provider or pharmacist when you get a new medicine. Tell your study doctor immediately if you plan the use or take any of the following:

- Non-prescription or over the counter drugs (such as Tylenol, cold, or allergy medicine)
- Grapefruit or Grapefruit juice
- Vitamins
- Health supplements (such as essential oils)
- Street drugs (such as cocaine, marijuana, or ecstasy/molly)

Make sure to tell your healthcare provider if you take any of the following medicines:

- Ketoconazole or Itraconazole
- Rifampin
- St. John's wort
- Cyclosporine
- Carbamazepine
- Efavirenz
- Clarithromycin
- Phenytoin
- Etravirine

It's very important to speak to your study doctor before taking any new medicines or drugs from the lists above during this study.

Vaccines

A vaccine is a shot that healthy people get to protect them from certain diseases. Some vaccines may cause mild reactions, such as soreness or fever. These risks are small compared to the risks of the disease the vaccine can prevent.

There are no known interactions between atogepant and the approved COVID-19 vaccines, or with other vaccines. Based on limited data from people who have received COVID-19 vaccines during clinical trials of atogepant, and the way that atogepant works, no interactions are expected between atogepant and COVID-19 vaccines.

Unknown risks

Since we are continuing to study this medicine, it is possible that there are side effects and long-term effects from atogepant that we do not know about and are not listed here.

Remember to contact your study doctor about:

- Side effects, problems with your health, or changes in the way you feel
- Signs you are allergic to atogepant, such as swelling or difficulty breathing
- If you seek emergency treatment due to a life-threatening allergic reaction
- If you or your partner has become pregnant
- If you are planning to take a new medicine, vitamin, health supplement, or street drug
- Questions about the study drug or study

Use and Storage of PK Samples:

Your PK samples will be studied to measure the amount of study drugs in the body at different time points. AbbVie (or people or companies working with AbbVie) will store the samples in a secure storage space with measures to protect confidentiality. The samples and data may be analysed and used by AbbVie (or people or companies working with AbbVie) while research continues as described in this form and will be stored until the end of the study when analysis is completed. Your samples and related data will only be used by AbbVie (or people or companies working with AbbVie) for the purposes described in this form. Your samples will be destroyed at the end of the study.

What are the possible benefits of taking part?

We hope that the treatment will help you, however this cannot be guaranteed. No one can know whether you will benefit from the treatment. It is possible that your condition may not improve or may worsen while taking part in this study. The information from this study may help researchers learn more about the study medication and may help to improve the treatment of people with this condition in the future.

What happens when the research study stops?
If you have to leave this study for medical reasons or AbbVie or your doctor wishes to withdraw you from this study, you will be asked to visit your study doctor for an End of Study/Early Termination visit.

Continued Treatment for Trial Participants After Study Completion:
The study product, atogepant, will be given to you only during this study and not after the study is over. Following completion of this study, your doctor will discuss treatment options available to you.

Study results
A summary of study results will be available for you to access on the "Results Summaries for Study Participants" page at AbbVie.com and on the "research summaries" page on the Health Research Authority (HRA) website at www.hra.nhs.uk. These will be available approximately a year or more after the trial has been fully completed and you will be provided with the estimated date for this at the end of your participation in the study.

Payments, expenses and costs
You will not be paid for taking part in this study, but you will be reimbursed for reasonable travel expenses, meals you incur to attend study visits you complete. All expenses must be supported by original receipts or tickets.

You will not have to pay for the study drug or for any tests, procedures or medications that are required by this study.

AbbVie is not required to share any profits in relation to the development of new tests, procedures and commercial products with you.

Third-Party Services:
AbbVie hired a company to assist in providing certain services to support your participation in this study. In order to provide these services, the company will need to process certain personal information about you, as described below. Additional information on how your personal information will be used and shared as part of your participation in this study, including your data protection rights, can be found in the 'INFORMATION, CONFIDENTIALITY AND DATA PROTECTION' section in PART 2.

The personal information that is needed by the company will depend upon the services being provided:

Reimbursement via Direct Deposit
To provide your study-related reimbursements/payments described in this form, the company will directly deposit funds into your bank account. In order to transfer funds, the company will need your name, address, date of birth, and bank account details.

Study-Related Travel
For approved travel, you or the site staff will book your travel arrangements through a designated travel agent, and the costs for such travel arrangements will be paid directly by AbbVie. In order to book travel and provide you with itineraries, the company and travel agent will need your name, address, date of birth, and email. Additional information may be required by the travel agent to complete the booking.

If third-party services are not used, then you may be reimbursed for your travel expenses by the site directly.

What if there is a problem?

Any complaint about the way you have been dealt with during this study is addressed in Part 2 of this Patient Information Sheet.

If the information in Part 1 has interested you and you are considering participating in this study, please read the additional information in Part 2 before making any decision.

Appendix A

Study Activities – Double-blind Treatment, Open-label Treatment, and Safety Follow-up Periods

	V1	V2	V3	V4	V5	V6	V7	V8	End of DB Treatment Period Visit
	Screening Up to 35 Days	Randomization	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 End of Study/Early Termination	
	Clinic Visit	Clinic Visit	Phone Visit	Clinic Visit	Phone Visit	Clinic Visit	Phone Visit	Clinic Visit	Clinic Visit
Informed consent	✓								
Personal information e.g. name, date of birth and race	✓								
Health and Medication Questions	✓	✓	✓	✓	✓	✓	✓	✓	✓
Columbia - Suicide Severity Rating Scale	✓	✓	✓	✓	✓	✓	✓	✓	✓
Complete your eDiary	✓ (Training only)	✓ (To be completed each time a qualifying migraine attack occurs and is treated with study drug)							
Review of eDiary		✓	✓	✓	✓	✓	✓	✓	✓
Complete subject paper cards		✓							✓
Review of side effects		✓	✓	✓	✓	✓	✓	✓	✓
Electrocardiogram (ECG)	✓							✓	✓
Vital signs	✓	✓		✓		✓		✓	✓
Physical examination	✓							✓	
Pregnancy test (Blood sample for screening only and urine sample for all other visits)	✓	✓		✓		✓		✓	✓
Laboratory tests (Blood and urine samples)	✓	✓		✓		✓		✓	✓
Collect PK Dried Blood Sample (DBS)		✓ (Training only)	✓ (To be collected while treating first qualifying migraine attack)						
Dispense study drug		✓							✓
Bring study drug blister card packaging, including unused study drug to clinic visit				✓		✓		✓	✓

PART 2

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your study doctor will tell you and talk to you about whether you should stay in the study. If you decide not to carry on, or your study doctor thinks it is better for you to stop the study, your study doctor will make arrangements for your care to continue. If you decide to stay in this study, he will ask you to sign an updated consent form.

If this study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What if there is a problem?

If you have a concern about any aspect of this study you should speak with the study staff who will do their best to answer your questions. Their contact details are found on the first page, with additional details at the end of this Patient Information Sheet.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event of you becoming ill or injured as a direct result of your taking part in this study, AbbVie agrees to provide compensation in accordance with the Clinical Trial Compensation guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking, the ABPI guidelines recommend that the sponsor (AbbVie), without legal commitment should reasonably compensate you for study related injuries without you having to prove that sponsor is at fault. This applies in cases where it is likely that such injury results from giving any new drug under trial or any procedure carried out in accordance with the procedures described in the study protocol. Consequently, AbbVie will not compensate you where such injury (i) results from any procedure carried out which is not in accordance with the study protocol; (ii) in case of wrongful acts by the study personnel, or (iii) if you do not follow instructions of your study doctor. By signing this form you are not losing any of your legal rights, including right to claim compensation for injury caused by negligence.

INFORMATION, CONFIDENTIALITY AND DATA PROTECTION

This confidentiality section describes your rights and explains how personal information about you including information derived from your biological samples and other information about your health. This type of information is referred to as "**Personal Data**" and it is protected by applicable data protection law. AbbVie and the study doctor and staff working on this study must comply with this law. Before Personal Data is transferred to AbbVie, the study doctor and staff will replace any information that could directly identify you (such as your name, address, and contact information) with a generic code which AbbVie cannot link to your identity. Personal Data without identifying information is referred to as "**Coded Data"**. Sponsor is the data controller of the Personal Data collected or created for the purposes of the study because the Sponsor is responsible for deciding what Personal Data will be collected for the study and how it will be used. This includes both the Coded Data shared with AbbVie, as well as Personal Data contained in the study documents maintained at the study site. The study site and study doctor will continue to be the data controllers of Personal Data contained in your medical records because they are responsible for deciding how your Personal Data will be used for your medical care that is unrelated to this study.

In this section we explain how we collect, use and share your Personal Data with others if you participate in the study. If you don't agree, you will not be able to participate in the study.

What Personal Data about me will be Collected?

To help answer the research questions, the study doctor and staff will collect Personal Data about you from you and your existing medical records so that they can understand your medical history. In addition, they may collect your Personal Data from available public records. Also, during the study, they will collect information self-reported by you as well as their observations of you.

The following are examples of Personal Data that may be collected and disclosed by the study doctor and staff responsible for your treatment:

- your name, address, telephone number, date of birth, race/ethnicity, medical record numbers and/or other identifying information
- results of examinations and laboratory tests including blood tests
- information regarding your health and medical history, including information derived from your biological samples (for example, blood, urine, and tissue), health conditions, treatments and medical procedures, and survival status, including related dates

AbbVie will only receive Coded Data and will not be able to directly identify you.

How will my Personal Data be used?

Listed below are examples of how your Personal Data may be used for the purposes of this (if you agree to participate):

- to determine if you can participate in this study;
- to evaluate how your health changes during the study and compare it to other study participants;
- to find out if treatment with the study drug is safe and effective and to follow up with you if needed for safety reasons after the study is completed;
- to learn more about the disease(s) or health condition(s) that are the subject of the study;
- to report safety data, such as adverse reactions or events, product complaints, or pregnancies, related to a medical product and/or device used in this study to its manufacturer;
- to provide you with reimbursement of your travel expenses for attending study visits; and
- to provide you with treatment and reimbursement of medical expenses in the event of a study-related illness or injury.

Your Coded Data collected for this study may also be used in continued medical research projects, the specific details of which may not be known at present. They could include:

- further examination of the safety or efficacy of any medical product or treatment included in the study;
- identification of new medical uses of any medical product or treatment included in the study;
- further examination of the disease(s) or condition(s) that are the subject of the study or similar diseases or conditions; and
- analysis of how AbbVie can improve its clinical research processes.

Your Coded Data is used to conduct research to improve health and care. As a pharmaceutical company, AbbVie has a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. AbbVie may also use your Coded Data if required to comply with a legal obligation.

Who will receive my Personal Data and biological samples?

The study doctor and staff will share your Coded Data and biological samples with AbbVie and its representatives for the purposes described above. The study doctor and AbbVie may share your Coded Data and biological samples with AbbVie's affiliates, as well as with its research partners in countries around the world.

The study doctor and staff may share your Personal Data and AbbVie may share your Coded Data with regulatory authorities in countries around the world and with the ethics committee responsible for oversight of this study.

These bodies are responsible for ensuring that the research is being conducted properly, in accordance with laws and ethical requirements, and they may use your Personal Data/Coded Data in order to fulfil their duties. Regulatory authorities may also use your Personal Data/Coded Data to evaluate and confirm the validity of the study findings.

AbbVie may share Personal Data contained in safety data with the manufacturer of the medical product and/or device used in this study. AbbVie shares safety data with the manufacturer based on its legitimate interest in supporting safety reporting requirements.

The results of this study may be published in study reports or scientific presentations and publications. Information that identifies you or that reasonably could be used to identify you will not be included in such reports, presentations and publications.

How will my Personal Data and biological samples be protected?

The study doctor and staff will store your Personal Data in a limited-access, secure storage space. They are required by law to protect the confidentiality of your Personal Data and to use and disclose it only as described in this document. Representatives of AbbVie, regulatory authorities, and the ethics committee overseeing this study may be provided with access to Personal Data controlled by the study site to verify that the study data is being reported accurately and that the study is being conducted properly. The study doctor will retain your Personal Data for as long as required by local laws and regulations or for a longer period if required by an agreement with AbbVie.

AbbVie will store the Coded Data and biological samples that it receives in a limited-access, secure storage space. AbbVie has implemented security measures to prevent unauthorized individuals from accessing your Coded Data and biological samples. AbbVie will only use your Coded Data and biological samples for the purposes described in this document. Before sharing your Coded Data, AbbVie will require each of its affiliates or research partners to sign a written agreement requiring them to protect your Coded Data and use it only for the purposes described in this document. AbbVie may retain the Coded Data reported to it for as long as the study drug is used or longer if required by local laws and regulations, consistent with Good Clinical Practices (GCP) and clinical trial related laws and regulations.

Some of AbbVie's affiliates and research partners may be located outside your country where data protection laws may offer less protection. Any Coded Data that is transferred to AbbVie's parent company, AbbVie Inc., in the United States, or other AbbVie affiliates is done under internal privacy agreements. A copy can be obtained by sending an email to privacyoffice@abbvie.com. Any transfers of Coded Data to AbbVie's research partners outside your home country will be done in compliance with the international data transfer restrictions that apply.

Can I See My Study Records; what rights do I have?

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

Your rights to access, change or move your information are limited, as the study doctor and staff and AbbVie need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the information about you that was already obtained will be kept (please refer to the information below for more details.) To safeguard your rights, the minimum personally identifiable information possible will be used.

VOLUNTARY WITHDRAWAL

Can I change my mind?

Entering a research study is completely voluntary. You can decide not to take part in this study without giving a reason and without penalty or loss of benefits. If you start the study, you may stop at any time without further explanation. This study may be stopped without your consent, at any time and for any reason by AbbVie, the study doctor, the ethics committee or organisations that regulate research in the UK /Ireland or other countries.

If you want to take back your permission to use your biological samples or if you want to stop participating in the study for any reason, you must let the study doctor know either verbally or in writing. You will not lose any benefits to which you are otherwise entitled. It will not affect how your study doctor cares for you and he/she will make arrangements for your care to continue.

What will happen if I don't want to carry on with this study?

If at any time you decide to stop taking part in this study, you should talk to the study doctor so that you can stop safely. If you stop this study early it is in your own interests to return to your study doctor for a check-up.

When you come out of this study for any reason, all study medicines and study medicine containers, including those unused and empty must be returned to the study site. You will also be asked to return to the site so that the study doctor may perform some final checks, which may include a physical examination and/or laboratory tests.

If you are withdrawn from this study because you become pregnant, we will continue to follow up and collect information about your pregnancy, as described in this Patient Information Sheet. If you do not want to be contacted by your study doctor or have your medical records reviewed to collect information on your pregnancy after you have stopped participation in this study, you should inform your study doctor about this when you are withdrawn from the study.

What will happen to my biological samples and Personal Data?

Biological Samples

If you withdraw or are withdrawn from the study, the biological samples we have collected from you as part of the study will continue to be stored and analysed as described in this document unless you specifically withdraw your permission. If you withdraw your permission to use your biological samples, no new research work will be started, and your biological samples will be destroyed unless a regulatory authority requires AbbVie to keep them. If AbbVie and/or other researchers did any testing of your biological samples before you withdrew your permission, AbbVie will still use and disclose the test results and keep the data generated from your biological samples due to regulatory requirements that are designed to safeguard scientific integrity.

Personal Data

If you withdraw or are withdrawn from the study, the study doctor and staff may continue to follow up with you regarding your health status. If you are withdrawn because you become pregnant, the study doctor and staff will also collect information about your pregnancy. This information will include:

- Your date of last menstrual period
- General information about your past pregnancies which may include:
    - Number of pregnancies and their outcome
    - Number of elective or spontaneous abortions
- Information about your current pregnancy which may include:
    - Forms of birth control used
    - Estimated and actual date of delivery
    - Complications during pregnancy, labour or delivery

- After the baby is born:
    - Your baby's birth weight and length
    - Your baby's gender
    - Information about any birth defects that your baby has and any tests or procedures that were performed to diagnose them.

You can always withdraw your permission for the collection of your Personal Data or withdraw your permission to participate in the follow up. You should inform your study doctor about this when you withdraw or are withdrawn from the study.

Even if you withdraw your permission to participate in follow up or you withdraw your permission for the collection of your Personal Data, we may still collect a limited amount of new Personal Data (i) information about your survival status from available public records, and (ii) safety information that may be related to your participation in the study. We need to continue to collect this type of information because of legal and regulatory requirements and AbbVie's legitimate interests in the scientific research described in this consent form.

Even after your withdrawal, the study doctor and staff and AbbVie may be required to include your information in analysis and aggregate study results, but in a way that will not identify you.

Involvement of your General Practitioner/family doctor (GP)

If you decide to take part in this study, your study doctor will inform your GP about your participation. This is done to make sure all doctors having anything to do with your care are aware of the medicines or treatments you are taking. They can also tell your doctor if there is any medical reason why you should not take part in this study.

Who is organising and funding the research?

The research study is being organised and funded by AbbVie. AbbVie will pay your hospital for their services in conducting this study.

Who will review this study?

All research is looked at by an independent group of people, called the Research Ethics Committee to protect your safety, rights well-being and dignity. A favourable opinion has been obtained from North East - Tyne & Wear South REC for this study.

Further information and contact details

Please contact the study doctor below if you would like more information about any part of this study, , your rights as a participant or in the case of a study related injury.

Doctor: Dr Daniel Lashley

Address:
Re:Cognition Health Bristol
Unit 240, Phase 200
Aztec west
Bristol
BS32 4SY

Telephone: 01174623600 Option 1 (8.30am – 5.30pm Mon to Fri)

➔ **In the event of an emergency please contact:**

Telephone: PI mobile number: 07701087629
If you call is not answered, please text this number and Dr Lashley will get back to you as soon as he can

You can find out more about how your Coded Data and Personal Data is being used and shared by contacting the study site at compliance@re-cognitionhealh.com.
Alternatively, please contact our external Data Protection Officer:

Evalian Limited
West Lodge
Leylands Business Park
Colden Common
Hampshire
SO21 1TH

Email: dpo@evalian.co.uk
Phone: 03330 500 111

You have the right to object to the Personal Data processing activities described in this consent form that are based on AbbVie's legitimate interests.

AbbVie's Data Protection Officer can be contacted by going to abbvie.com/privacy-inquiry.html or by sending a letter to AbbVie Deutschland GmbH & Co. KG, Knollstraße, 67061 Ludwigshafen, Germany (Attn: DPO).

This Patient Information Sheet and Consent Form is governed by the laws of England and Scotland.

Thank you for taking the time to read this Patient Information Sheet.

Please let us know if you have any questions or if you would like further information.

Re:Cognition Health
Unit 240, Phase 200, Aztec West, Bristol, BS32 4SY United Kingdom
Telephone +44 (0)117 462 3600
bristol@re-cognitionhealth.com
www.recognitionhealth.com

Company number 06892124

Patient Initials:_____ Patient number:_____

CONSENT FORM

Study Title: Randomized, Double-Blind, Placebo-Controlled, Multiple-Attack Study with an Open-Label Extension to Evaluate the Efficacy, Safety, Tolerability, and the Consistency of Effect of Atogepant for the Acute Treatment of Migraine (ECLIPSE)

Principal Investigator: Dr Daniel Lashley

		Please initial each box
1	I confirm that I have read the Patient Information Sheet (version 3, 05-Mar-2024) and all my questions regarding participation in this research study have been answered.	☐
2	I understand that relevant sections of my medical notes and data collected during this study may be looked at by the study doctor, personnel helping the study doctor to conduct this study and, individuals from AbbVie, their representatives/ agents, and regulatory authorities.	☐
3	I acknowledge that my Personal Data and biological samples will be accessed, collected, processed and transferred as described in the Patient Information Sheet.	☐
4	I understand that I *or my legal representative* will receive a copy of this signed and dated Patient Information Sheet and Consent Form.	☐
5	I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	☐
6	I agree to my GP being informed that I am taking part in this study and for my GP to provide personal health information that is relevant to my participation in this study, such as other medicines I am taking.	☐
7	I agree to take part in this study.	☐
	Text Message Reminders	
8	I consent to receive recurring text messages from AbbVie and companies working on AbbVie's behalf, including study related reminders, to the number indicated below. Message and data rates apply. My consent is not a condition for study participation or to receive other goods and services. I can text STOP to opt-out at any time. Mobile/Cell Phone Number (Including Area Code): _____	☐
9	I do not consent to Text Message Reminders	☐

_____ ____/____/____ _____

Patient Name (print) Date Patient Signature

I have fully informed and discussed with the participant this study, and possible benefits and risks. The patient has been given enough time to read the information and appears to understand the nature and purpose of this study.

_____ ____/____/____ _____

Investigator Name (print) Date Investigator Signature
(Investigator conducting informed consent discussion)

Additional Signature if applicable:

Add role and reason for additional signature requirement (eg. Translator, impartial witness)

_____

_____

_____

_____

_____ __ __/____/____ _____

Name (print) Date Signature

When completed; 1 for patient [or 1 for legal representative]; 1 for medical notes; original to be kept in Investigator Site File