PARTICIPANT INFORMATION SHEET

Study Title:	A Randomized, Double-Blind, Placebo-Controlled Trial of Adjunctive Troriluzole in Obsessive Compulsive Disorder
IRAS ID Number:	294656
Study Code:	BHV4157-303
Study Sponsor:	Biohaven Pharmaceuticals, Inc.
Investigator:	Dr Joshua Asubiaro
Study centre Address:	Bioluminux Research, 15 Diamond Court, Opal Drive, Fox Milnes, Milton Keynes MK15 0DU
Study-related phone number(s):	Phone Number: +441908 985540 Phone Number (24 Hours): +447340774604

Key Information

This form contains information that will help you decide whether to take part in this study. Most important information from the study is presented below:

- Taking part in this study is completely voluntary. You should talk about any questions or concerns you have with the study staff before deciding to participate.
- If you decide to participate, you can leave the study at any time for any reason with no penalty or loss of medical care benefits, and with no effect on future medical care.
- This is a clinical research study, which means scientists are trying to learn new information about a disease or condition and a possible new treatment for it. Clinical research studies have different risks than regular medical care. You should discuss and think about these risks before you join any research study.
- The purpose of this clinical research study is:
  - evaluate the difference in how troriluzole works compared to placebo on your obsessive compulsive disorder (OCD) symptoms;
  - evaluate how safe and well tolerated troriluzole is when administered as a single dose of 280 mg; and
  - evaluate how troriluzole works compared to placebo using scales that assess other aspects of your health that may be affected by OCD.
- OCD is a pattern of unreasonable thoughts and fears (obsessions) that can lead to repetitive behaviours (compulsions). These obsessions and compulsions can interfere with daily activities. Up to 60% of patients with OCD do not have an adequate response to approved oral treatments.
- Troriluzole is an investigational drug, which means that it has not been placed on the market yet and it is not yet approved by any Health Authority worldwide for the treatment of OCD or other diseases.
- About 700 male and female participants (18-65 years old) with OCD will participate in this study. The study will last for approximately 18 weeks with up to 7 study visits to the study centre.

- While on this study, you need to avoid certain medications including over-the-counter medications, vitamins and herbal substances. You must follow contraceptive precautions and cannot plan to mother or father a child about 30 days before the study begins and 30 days (90 days for male participants) after receiving last study dose. Details are discussed in the document under Section 6 (What does this study demand from you beyond the routine practice?) and Section 7 (What are the possible risks, side effects and discomforts of participating in this study?)
- The main activities in this study are providing consent to participate; performing tests to check your health throughout the study (such as physical exams, electrocardiogram (ECG) testing, collection of urine, and blood draws for laboratory testing); study drug dosing; and performing tests and completing questionnaires to assess symptoms of your OCD. Details are presented in Section 5 (What will happen to you during this study?)
- There have not been most commonly reported side effects (sometimes called adverse effects) with troriluzole in the human studies so far however, common side effects and deaths noted in the studies are discussed under the Section 7 (What are the possible risks, side effects and discomforts of participating in this study?)..
- There may or may not be a direct benefit to you from your participation in this study. Your participation in this study will contribute to increasing information that may help treating patients with OCD and may contribute to improvements in medicine in general..
- In this research study we will use information from you, your medical records, and your General Practitioner (GP). We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
  - Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
  - At the end of the study, we will save some of the data in case we need to check it and remaining biological samples if any will not be used for future studies and will be destroyed.
  - We will make sure no-one can work out who you are from the reports we write.
  - The information pack tells you more about this. Details are discussed under the Section 13 (Will my participation in this study be kept confidential?)
- Information on your participation in the study, medications that can be used and should be avoided will be shared with your GP and other doctors you regularly consult.
- The Sponsor has stipulated insurance coverage (Insurance policy number: 36064415) with the Company Armfield, Harrison & Thomas, LLC, for any side effects resulting from this study in accordance with current legislation. Details are discussed under the Section 12 (What if something goes wrong?)
- You will continue to be treated for your OCD in this study. There may be alternative procedures or treatment options available to treat your condition. Speak with your doctor to learn more about these possible options to help you decide if participating in this study is the right decision for you at this time.

Table of Contents

1. INVITATION TO TAKE PART IN A CLINICAL RESEARCH STUDY

We would like to invite you to take part in a clinical research study which is organized and funded by Biohaven Pharmaceuticals, Inc. from the United States of America. This research study is investigating troriluzole (BHV-4157) in participants with OCD.

Clinical studies are research activities and are performed to investigate new drugs that are under development for the treatment of diseases. They include only participants who voluntarily choose to take part.

Before you decide whether you want to take part, it is important for you to read and understand this consent document. It describes the purpose, procedures, benefits, risks,

discomforts, and precautions of the study. No guarantees can be made about the results of this study. Please take the time to read the following information carefully. Feel free to discuss it with your General Practitioner (GP), family, and friends. Ask your study doctor to explain anything that is not clear to you, or if you would like to get more information. Please refer to the first page of this document for contact details of the study doctor. Take time to decide whether you wish to take part. This Information Sheet has been designed to give you all the relevant information you need before deciding whether to take part in this study or not.

It is up to you to decide if you want to take part. If you decide to take part in this study, you will be asked to sign the Informed Consent Form. By signing it you will confirm that you have understood the information given to you and that you voluntarily agree to take part in this study. No study-related procedures will be initiated until you have agreed to them by reading, signing, and dating the Informed Consent Form. A copy of the completed Informed Consent Form will be kept in your medical records. If you decide to take part in the study, then you are still be free to leave the study at any time without losing any healthcare benefits to which you are otherwise entitled and without having to give any reason. You should inform your study doctor if you are thinking about leaving the study, so that he/she can tell you how to discontinue from the study safely and discuss what follow-up care and testing would be most needed. If you decide not to take part in the study, there will be no impact to your current or future healthcare.

Also, please note that the study doctor can discontinue you from the study at any time if he/she believes it is in the best interest of your health, if you do not follow the study rules, or if the study is stopped for any reason.

The Medicines and Healthcare Products Regulatory Agency (MHRA), UK has approved the use of troriluzole for this study. The Research Ethics Committee (EC) has approved the information in this consent document and has given the study doctor approval to do the study. An EC is an independent committee that helps protect the rights of research participants. Although the EC has approved the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean that the EC has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

2. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS CLINICAL RESEARCH STUDY?

You have been asked to take part in this study because you have been diagnosed with OCD. OCD is a pattern of unreasonable thoughts and fears (obsessions) that can lead to repetitive behaviours (compulsions). These obsessions and compulsions can interfere with daily activities. Up to 60% of patients with OCD do not have an adequate response to approved oral treatments.

Your study doctor has determined that you may qualify for the study and is offering you the possibility to take part in this study where a new treatment for your disease is being investigated. If you choose to take part and are suitable to do so, you will receive the investigational drug called troriluzole or placebo, for 10 weeks.

3. WHAT IS THE DRUG BEING TESTED AND WHAT IS THE PURPOSE OF THE STUDY?

Troriluzole is an investigational drug, which means it has not been placed on the market yet and it is not yet approved by the, The Medicines and Healthcare Products Regulatory Agency (MHRA), European Medicines Agency (EMA), US Food and Drug Administration (FDA) or any Health Authority worldwide for the treatment of OCD. This drug is therefore considered experimental.

Troriluzole works through its main metabolite (called riluzole) which is thought to target mechanisms in the brain causing obsessions and compulsions associated with OCD. Troriluzole was developed to be a safer, more convenient form of riluzole (approved by FDA, EMA, MHRA and other Health Authorities for the treatment of amyotrophic lateral sclerosis). Troriluzole is developed by Biohaven Pharmaceuticals, Inc.

To be eligible to take part in screening you must be on a stable dose of a single standard of care medication for OCD and experiencing an inadequate response. If you fulfil the eligibility criteria, you will be randomly (like the flip of a coin) assigned to receive either placebo (which looks like the study drug but contains no active ingredients and therefore is not expected to have an effect) or troriluzole (280 mg, after two weeks of 200 mg) to take in addition to your current standard of care medication for OCD.

The study will also include an additional test, a so-called pharmacogenomics test performed at Baseline visit and again at the Week 10 visit. The study doctor may ask you whether you want to take part in this additional test or not. The pharmacogenomics test samples are voluntary and will be used in future research. Samples collected are considered as donations from the study participants, and as such, participants will not be involved in any future research, not will participants benefit directly from the use of the donated samples. The results of any future will used for the advancement of OCD research. The performance of this test will not influence your health. If you, however, decide to take part in this pharmacogenetic testing, then you will be required to provide a blood sample of approximately 6 mL (approximately half a tablespoon of blood) each time, at Baseline and at the Week 10 visit. This sample will be in addition to blood samples that will be drawn for the purposes of your medical care of the main clinical trial.

The optional pharmacogenomic blood samples will be stored at the Central Laboratory (ACM Global Laboratories) until the end of the study, after which the samples will be sent to Syneos Health to be stored indefinitely for use in pharmacogenetic research. If you decide to take part in the pharmacogenetic testing, you will be asked to sign an additional informed consent along with this consent form. Your study doctor will discuss this with you.

The purpose of this study is to

1. evaluate the difference in how troriluzole works compared to placebo on your OCD symptoms;
2. evaluate how safe and well tolerated troriluzole is when administered as a single dose of 280 mg; and
3. evaluate how troriluzole works compared to placebo using scales that assess other aspects of your health that may be affected by OCD.

4. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is expected that approximately 700 male and female participants (18 - 65 years old) suffering from OCD globally will take part in this study. In the United Kingdom (UK) about 49 participants are expected to participate in this study. The study will be conducted at approximately 100 investigational sites in several countries including the US, the UK, the Netherlands, Italy, Spain, and Canada. The list of countries and investigational sites may change during the course of the study.

5. WHAT WILL HAPPEN TO YOU DURING THIS STUDY?

Your study participation will last for up to 18 weeks and will include approximately 7 study visits to the study centre.

The study will consist of the following phases:

- Screening Phase (up to 42 days) – 1 visit;
- Randomization Phase (10 weeks) – 5 visits (Baseline, Weeks 2, 4, 8, 10);
- Follow-up (2 weeks) – 1 visit.

Screening Phase (Visit 1; up to 42 days before Baseline Visit):

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

- You will be asked about your past medical history including your OCD symptoms and any family history of OCD.
- You will have a physical examination performed by your study doctor.
- You will be measured for height and weight and have your vital signs taken.
- You will have an electrocardiogram (ECG) which tests the functions of your heart.
- Your study doctor will speak with you about any medications you can and cannot take while on the study, including any over the counter medication, vitamins, or herbal medications or supplements.
- Your study doctor will ask you questions about suicidality (for example thoughts of harming yourself).
- You will be asked to complete questionnaires about how you are feeling and about your OCD. Each questionnaire listed in this study may require as little as 5 minutes or as much as 30 minutes to complete.
- You will be asked questions about the severity of your OCD and questions about your obsessions and compulsions. All the information shared will be kept confidential as applicable by law and if needed by law the confidentiality will be broken should you disclose any information about potential harm to either yourself or others. This is only for your and others safety.
- You will have blood samples drawn, and tested for chemistry, hematology, HIV, liver function, hepatitis B and C and syphilis infection which is a sexually transmitted disease. The study doctor may be required by law to report the result of these tests to the local health authority. The total amount of blood drawn during this visit will be

approximately 18 to 20 mL (approximately 1 to 2 tablespoons). Over the course of the study, the total volume of blood drawn (for all your blood taken for the study) will be less than 80 mL or approximately 6 tablespoons. In comparison, a blood donation generally represents approximately 450 mL (approximately 31 tablespoons or 2 cups or 1 pint) of blood, and it is done all in one (1) day. Blood is tested for chemistry, haematology, liver function, and to understand what the body does to the study drug. Urine is tested for drug, urinalysis, and pregnancy (in women of childbearing potential [WOCBP]). Serum pregnancy test is done to confirm pregnancy if any.

- You will need to provide a urine sample for urinalysis and drug testing.
- If you are a woman of childbearing potential a pregnancy test will be performed on your blood at this visit to confirm you are not pregnant

Once you finish this screening visit, the study doctor will wait for the test results. If you meet the criteria required to enter the study your study doctor will schedule your next visit within forty-two (42) days or sooner.

During the Screening Phase of the study, which is after Visit 1 but before Visit 2, an additional assessment of your OCD symptoms and medication history will be conducted by a phone call. The study staff will help to arrange this phone call and provide you with information regarding when this phone call is scheduled based on your availability. This phone call will be conducted by qualified personnel to confirm your eligibility for the study. The call is expected to take up to approximately 1 hour.

If you qualify to take part in this study and go on to receive the study treatment, then the "Randomization Phase" will begin.

The procedures carried out at this visit are mentioned in the Schedule of Study Events table.

Randomization Phase (Baseline, Weeks 2, 4, 8, 10):

During "Randomization Phase" the following will happen:

- You will have your vital signs taken.
- You will have an ECG which tests the functions of your heart.
- Your study doctor will speak with you about any medications you can and cannot take while on the study, including any over the counter or herbal medications or supplements.
- Similar to Visit 1, your study doctor will ask you questions about suicidality.
- Similar to Visit 1, you will be asked to complete questionnaires about how you are feeling and about your OCD.
- You will have blood samples drawn and tested for chemistry, hematology, and pharmacokinetics (to measure the amount of troriluzole in your blood). The total amount of blood drawn during this Randomization Phase will be approximately 56 mL (approximately 4 tablespoons).
- You will need to provide a urine sample for urinalysis and drug testing.
- If you are a woman of childbearing potential (WOCBP) a pregnancy test will be performed on your urine to confirm you are not pregnant before receiving any study drug.
- If you are a woman of childbearing potential a confirmatory pregnancy test will be performed on your blood at the central laboratory to confirm you are not pregnant.
- Your study doctor will ask you about any symptoms or changes since your last visit and any medications you have taken other than the study drug since your last visit.

You will need to keep track of all medications both over the counter and prescription, herbal medications or supplements and report them to the study staff at each visit. If you need to start a new medication during the study you should contact the study staff first before taking the new medication.

- If the study doctor assesses you to be ready to continue in the study, the study drug (treatment or placebo) will be dispensed to you, and the study doctor, or the study staff will review with you how to take the study drug each day. You should take the study drug on a regular basis and at the same time of the day. If a dose is missed, take the next dose as originally planned. The study drug should be stored at temperatures between 20° and 25°C and protected from bright light.

You will be asked to return all study drug bottles (used and unused) to the study site at each visit.

Details on what procedure is performed at each visit, is listed in the "Schedule of Study Events" table.

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

You will receive either 200 mg (provided as 100 mg capsules in a single bottle) of troriluzole or matching placebo capsules. You will be instructed to take two (2) capsules of the study drug every morning. The first dose should be taken the morning after the baseline visit (Visit 2). If you have difficulty tolerating the study drug between visits you will have to contact the study staff.

Your study doctor or study staff will schedule you to come back to the study site in two (2) weeks.
Visit 3 (Week 2): At this visit, the study doctor will increase the dose of your study drug. You will receive either 280 mg (provided as 140 mg capsules in a single bottle) of troriluzole or matching placebo capsules. You will be instructed to take two (2) capsules of the study drug every morning. If you have difficulty tolerating the study drug between visits, you should contact the study staff.

Your study doctor or study staff will schedule you to come back to the study site in two (2) weeks.

Visit 4 (Week 4): If you are able to schedule this study visit in the morning your study doctor may instruct you to hold that morning's dose until after your blood is drawn to obtain the lowest level of study drug in your blood. This is not mandatory, and you can decide not to do this, so you should discuss with your study doctor whether this is appropriate or possible for your visits. At this visit you will need to provide the study staff with the date and time you took your last dose of study drug. Additionally, you will need to tell the study staff if you ate a meal within two (2) hours of that last dose.

The total amount of blood drawn during this visit will be approximately 12 mL (approximately 1 tablespoon).
You will receive either 280 mg (provided as two bottles of 140 mg capsules) or matching placebo. You should take two (2) capsules from the first bottle, until empty, then two (2)

capsules from the second bottle, at the same time, every morning. If you have difficulty tolerating the study drug between visits you should contact the study staff.

Your study doctor or study staff will schedule you to come back to the study site in four (4) weeks.

Visit 5 (Week 8): If you are able to schedule this study visit in the morning your study doctor may instruct you to hold that morning's dose until after your blood is drawn to obtain the lowest level of study drug in your blood. This is not mandatory, and you can decide not to do this, so you should discuss with your study doctor whether this is appropriate or possible for your visits. At this visit you will need to provide the study staff with the date and time you took your last dose of the study drug. Additionally, you will need to tell the study staff if you ate a meal within two (2) hours of that last dose.

The total amount of blood drawn during this visit will be approximately 12 mL (approximately 1 tablespoon). You will receive either 280 mg (provided as 140 mg capsules in a single bottle) of troriluzole or matching placebo capsules. You will be instructed to take two (2) capsules of the study drug every morning. If you have difficulty tolerating the study drug between visits you should contact the study staff.

After all the tests are completed, if the study doctor assesses you to be ready to continue in the study, you will be given the study drug and asked to return in two (2) weeks.

Visit 6 (Week 10 or early termination): If you are able to schedule this study visit in the morning, your study doctor may instruct you to hold that morning's dose until after your blood is drawn to obtain the lowest level of study drug in your blood. This is not mandatory, and you can decide not to do this, so you should discuss with your study doctor whether this is appropriate or possible for your visits. At this visit you will need to provide the study staff with the date and time you took your last dose of study drug. Additionally, you will need to tell the study staff if you ate a meal within two (2) hours of that last dose.

A blood sample will also be taken at this visit for pharmacokinetics (to measure the amount of troriluzole in your blood). The total amount of blood during this visit will be approximately 18 to 20 mL (approximately 1 to 2 tablespoons).

After you complete the Week 10 Visit, the double-blind, Randomization Phase of the study is completed.

Details on what procedure is performed at each visit, is listed in the "Schedule of Study Events" table.

Follow-up Visit (2-Week Post Final Dose)

You do not need to have this Follow-up Visit if you go directly into the Open-Label Extension phase of the study. During this open-label extension study (study code: BHV4157-209), all the eligible participants will receive troriluzole treatment for 48 weeks.

If you are not eligible or choose not to continue in the study or need to be discontinued from the study at any time, you will be asked to come back in two weeks for a Follow-up Visit.

- You will have a physical exam performed by your study doctor.
- You will have an ECG performed which tests the functions of your heart.
- You will have your vital signs taken.

- You will have blood samples drawn, and tested for chemistry, and haematology. The total amount of blood drawn during this visit will be approximately 12 mL (approximately 1 tablespoon).
- Your study doctor will ask you questions about suicidality.
- Your study doctor will ask you about any symptoms or changes since your last visit and any medications you have taken other than the study drug since your last visit.
- You will need to provide a urine sample for urinalysis.
- If you are a WOCBP a pregnancy test will be performed on your urine at this visit to confirm that you are not pregnant.
- If your urine pregnancy test is positive a confirmatory pregnancy test will be performed on your blood at the central laboratory.

Your study doctor will ask you questions about suicidality (for example thoughts of harming yourself).

- If you are having suicidal thoughts, call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call emergency contact number 111 and/or a national confidential suicide helpline at: Samaritans 116 123.

The total study treatment period will be ten (10) weeks, after which participants will return to the clinic two (2) weeks after discontinuing the study drug for a follow up safety visit or if eligible, will take part in the Open Label Extension Study.

At any time during the study if the study doctor feels additional tests or visits will be beneficial for your health then you may be asked to come more often.

Details on what procedure is performed at each visit, is listed in the “Schedule of Study Events” table below.

Schedule of Study Events

Visit	Screening	Baseline	Week 2	Week 4	Week 8	Week 10 or ET	Week 2 Post Last Dose
Day	**up to -42**	**0**	**14[a]**	**28[a]**	**56[a]**	**70[a]**	**84[a]**
Informed Consent and Pharmacogenetic Informed Consent	X						
Inclusion/Exclusion	X	X					
Mini International Neuropsychiatric Interview (MINI)	X						
Borderline Personality Disorder Module (BPD Module)	X						
Massachusetts General Hospital-Treatment Response Questionnaire for OCD (MGH-TRQ-OCD)	X						
Medical History, Demographic Assessment, Disease History, and SAFER Interview	X						
Adverse Event Assessment	X	X	X	X	X	X	X
Laboratory Assessments including urinalysis	X	X		X	X	X	X
Serology	X						
Serum pregnancy testing	X	X		X	X	X	X
Urine pregnancy testing		X	X	X	X	X	X
Urine drug test	X	X				X	
Complete Physical Exam	X					X	X
Physical Measurements	X					X	
Vital Signs	X	X	X	X	X	X	X
12-Lead Electrocardiogram	X	X		X		X	X
Concomitant Medication Review	X	X	X	X	X	X	X
Columbia-Suicide Severity Rating Scale (C-SSRS)	X	X	X	X	X	X	X
Placebo-Control Reminder Script (PCRS)		X		X	X	X	
Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)	X	X		X	X	X	
Clinical Global Impressions-Improvement Scale (CGI-I)				X	X	X	
Clinical Global Impressions-Severity Scale (CGI-S)	X	X		X	X	X	

Visit	Screening	Baseline	Week 2	Week 4	Week 8	Week 10 or ET	Week 2 Post Last Dose
Day	**up to -42**	**0**	**14[a]**	**28[a]**	**56[a]**	**70[a]**	**84[a]**
Sheehan Disability Scale (SDS)	X	X		X	X	X	
Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR)	X	X		X	X	X	
Beck Anxiety Inventory (BAI)	X	X		X	X	X	
Brown Assessment of Beliefs (BABS)	X	X				X	
Dimensional Obsessive Compulsive Scale (DOCS)		X		X	X	X	
Pharmacokinetics Blood Sample				X	X	X	
Pharmacogenomics Blood Sample		X				X	
Randomization		X					
Dispense Study Drug		X	X	X	X		
Drug Accountability			X	X	X	X	

ET=early termination; [a] Visit window +/- 3 days

6. WHAT DOES THIS STUDY DEMAND FROM YOU BEYOND THE ROUTINE PRACTICE?

This study is going to be performed according to the recommendations of the international guidelines for diagnosis and treatment of OCD.

As part of this study, you will be required to visit the clinic more frequently than during the routine practice and you will be required to give more blood than usual. It is very important that you receive the study medication regularly, according to the specified schedule, so you will be obliged to visit the clinic according to a study schedule, which your doctor will provide to you.

Some medications and even the over-the-counter medications, homeopathic preparations and herbal supplements may interact with the study medication. It is therefore very important to ask your study doctor for permission before you take ANY medication. If your GP prescribes any medication, please notify your study doctor before taking it.
You are NOT allowed to take part in any other clinical study or experimental procedures during the course of this study.

COVID-19 EXPECTATIONS

1. **Duration of Participation**
   Duration of study treatment may be longer due to novel coronavirus (COVID-19) precautions.
2. **Study Procedures**
   The study visits in this study are relatively close together due to dose increases and necessary data to be collected. Therefore, there will not be a lot of flexibility with the COVID -19 pandemic, and you will be expected to come in for all visits whenever possible or may need to be discontinued. However, in some instances, the sponsor may be able to offer alternative options, such as lab tests being collected at a local lab, a safety phone call, and/or study drug being sent to your home. The sponsor and study site will follow local guidelines and review each request.

7. WHAT ARE THE POSSIBLE RISKS SIDE EFFECTS AND DISCOMFORTS OF PARTICIPATING IN THIS STUDY?

Like with all medications, the appearance of side effects (unwanted effects from the drug) is always possible. Taking part in a clinical research study involves some unforeseeable risks of side effects that could occur, sometimes called Adverse Events (AEs). The text below summarizes the clinical trial experiences with troriluzole and riluzole, including how many participants have been given the study drug and any AEs or experiences.

Troriluzole
The current safety data includes AEs reported as of Jun 28, 2022 by human participants in troriluzole clinical studies. These troriluzole studies include ten (10) completed clinical studies and seven (7) ongoing clinical studies. These clinical trials included approximately 1615 subjects who have received troriluzole: 216 healthy participants, 339 participants with spinocerebellar ataxia (SCA), 431 participants with OCD, 281 participants with Alzheimer's disease (AD), and 348 participants with generalized anxiety disorder (GAD). In both the

completed and on-going trials, safety data available to date for troriluzole suggests that it is well tolerated and can be safely administered at doses up to 280 mg daily.

There were fourteen (14) deaths reported as of Jun 28, 2022, due to reasons mentioned below so far in the clinical trials. All were considered not related to troriluzole.

- aspiration (2)
- respiratory failure (2)
- suicide
- lung cancer
- pneumonia (fluid in the lungs)
- subarachnoid haemorrhage (bleeding around the brain)
- electrical malfunction of the heart (heart attack)
- myocardial infarction
- gallbladder cancer
- leukemia (blood cancer)
- corona virus infection (2)
- subdural hematoma
- failure to thrive
- sepsis

The most common side effects reported by participants receiving Troriluzole are the following:

Very common (may affect more than 1 in 10 people, greater than 10%):

- None at this time

Common (may affect up to 1 in 10 people, greater than or equal to 1% through less than or equal to 10 %):

- Headache (7.6%)
- Fall (7.4%)
- Dizziness (6.5%)
- Fatigue (feeling tired) (6.4%)
- Nausea (5.4%)
- Urinary Tract Infection (UTI) (4.8%)
- Nasopharyngitis (common cold) (4.7%)
- Upper Respiratory Tract Infection (URI) (4.5%)
- Diarrhea (3.8%)
- Insomnia (trouble sleeping) (3.5%)
- Somnolence (drowsiness) (3.3%)
- Arthralgia (pain in a joint) (3.2%)
- COVID-19 (3.1%)
- Back pain (3.0%)
- Anxiety (2.9%)
- Muscle Spasms (2.5%)
- Decreased Appetite (2.2%)
- Cough (2.0%)
- Weight Decreased (1.8%)
- Constipation (1.7%)
- Contusion (bruise) (1.7%)
- Abdominal Pain (1.4%)
- Alanine Aminotransferase Increased (1.4%)
- Balance Disorder (1.4%)
- Oropharyngeal Pain (sore throat) (1.4%)
- Syncope (fainting) (1.4%)
- Depression (1.3%)
- Dry Mouth (1.3%)
- Skin Laceration (1.3%)
- Dyspepsia (indigestion) (1.3%)
- Gastro-esophageal Reflux Disease (GERD) (1.3%)
- Ligament Sprain (1.3%)
- Rash (1.2%)
- Vertigo (1.2%)
- Asthenia (weakness/lack of energy) (1.2%)
- Myalgia (1.2%)
- Weight increase (1.2%)
- Aspartate Aminotransferase Increased (1.2%)
- Bronchitis (1.1%)
- Skin abrasion (1.1%)

- Upper Abdominal Pain (1.7%)
- Influenza (1.7%)
- Pain in extremity (1.6%)
- Liver Function Test Increased (1.5%)
- Vomiting (1.5%)
- Abdominal Discomfort (1.5%)
- Sinusitis (sinus infection) (1.5%)
- Suicidal Ideation (1.5%)
- Hypertension (1.0%)
- Blood Creatine Phosphokinase Increased (1.0%)
- Pollakiuria (frequent urination) (1.0%)
- Tremor (1.0%)

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Riluzole

Following oral administration of troriluzole, the main active product from the study drug's biotransformation (or how the body breaks down the study drug) is known as riluzole.. It could be expected that side effects occurring following the administration of riluzole might happen after the administration of troriluzole.

The AEs associated with the regular use of riluzole by participants being treated for their medical condition are listed below.

Taking part in research often involves some risks of physical or psychological injury or discomfort.

The most likely risks of this study are described below. These deserve careful thought. This study may include risks that are unknown at this time.

Risks related to your normal medical care are not listed in this form. We encourage you to discuss these with your study doctor, your GP, or another healthcare professional.

The following AEs were seen in greater than or equal to 2% (except if otherwise stated) of the participants taking riluzole.

- Asthenia (physical weakness or lack of energy) (19%)
- Nausea (urge to vomit) (16%)
- Decreased lung function (10%)
- High blood pressure (5%)
- Abdominal pain (5%)
- Vomiting (4%)
- Arthralgia (joint pain) (4%)
- Dizziness (4%)
- Dry Mouth (4%)
- Insomnia (4%)
- Pruritus (itching skin) (4%)
- Tachycardia (rapid heart rate) (3%)
- Flatulence (gas) (3%)
- Increased cough (3%)
- Peripheral edema (swelling) (3%)
- Urinary Tract Infection (3%)
- Circumoral paresthesia (tingling/pricking sensation around the mouth) (2%)
- Somnolence (drowsy) (2%)
- Vertigo (sensation that environment is moving or spinning) (2%)
- Eczema (red/itchy skin) (2%)

Riluzole impaired fertility when administered to male and female rats prior to and during mating at an oral dose of 15 mg/kg, or 1.5 times the maximum approved daily dose of riluzole, and higher than the dose included in this study.

Other AEs have been reported with the administration of riluzole, but at a frequency lower than 2%.

Liver Injury: Rare cases of liver failure, some leading to death or liver transplant, have occurred with the use of riluzole. You must immediately contact a study doctor if you have any persistent symptoms of nausea, loss of appetite, fatigue, vomiting, right upper abdominal pain or jaundice, dark urine or pale stools. This may be a sign of liver failure.

Low level of white blood cells: Neutropenia, meaning one portion of your white blood cell test results are considered abnormal, can make you more prone to infections. Among approximately 4000 participants given riluzole for ALS, there were 3 cases of marked neutropenia (absolute neutrophil count less than 500/mm3), all seen within the first 2 months of riluzole treatment. **You must contact a study doctor to report any febrile illness (illness with a fever)**.

Interstitial lung disease and hypersensitivity pneumonitis: Cases of interstitial lung disease (scarring of the lung tissue) causing dry cough and/or difficulty breathing or hypersensitivity pneumonitis (inflammation of the lung tissue) have been reported in participants treated with riluzole, and some of these cases were severe; upon further investigation, many of these cases were hypersensitivity pneumonitis. **You must contact a study doctor if respiratory symptoms develop such as dry cough and/or difficulty breathing**.

If you receive placebo (the inactive substance) as part of this study, your symptoms of OCD may or may not improve or may get worse.

Since everyone is different, it is not possible to predict what AEs one may experience. Contact your study doctor immediately if you experience any AEs so that you can be treated as soon as possible. The dosage of treatment may be reduced, or the treatment may be stopped completely, if necessary. Please notify your study doctor about any AE you experience during the study.

Prohibited medications:
Prior use of riluzole is prohibited.
The use of the following medications is prohibited 30 days prior to randomization (baseline visit) and during the ENTIRE study.

- Medical or recreational marijuana;
- Cannabidiol (CBD) oil;
- Tricyclic antidepressants (with the exception of clomipramine);
- Monoamine-oxidase (MAO) inhibitors.

The use of the following medications is prohibited 4 weeks prior to screening and during the study: stimulants, neuroleptics, mood stabilizer and glutamate agents (e.g. gabapentin, pregabalin, topiramate, lamotrigine, N- acetylcysteine, ketamine, memantine, sodium valproate, lithium).

Troriluzole should be used with caution with medications that are inhibitors or inducers of the CYP1A2 enzyme system due to the potential for drug interactions, and be avoided with strong CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin).

Other medications: Other medications not explicitly called out herein are allowed during the study, provided they: have been prescribed for a sufficient duration (at least 30 days) that the investigator can adequately assess tolerability and deems them to be well-tolerated; (2) do not limit participant's ability to perform key rating scales by the impression of the investigator. (3) the regimen and dose (± 25%) have been stable for at least 30 days prior to screening and are not anticipated to change during the Randomization Phase; (4) could not adversely affect assessment of safety or efficacy.

Unexpected side effects
Since the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or foetus if you or your female partner become pregnant.

If you suffer any symptoms that you have not experienced before and are not listed above, you should contact your doctor as soon as possible.

The study doctor will provide all support to treat the AEs and any other side effects and follow up with you until they are resolved.

Pregnancy Risks
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 take part in this study**. Please inform the study doctor if this is the case.

Females:
In order to reduce the risk of pregnancy, you must agree to use highly effective birth control method starting 30 days before study treatment is taken, while you are participating in this

study and for 30 days after your last dose of the study drug.

WOCBP must agree to use highly effective birth control methods including two methods of preventing pregnancy, for the duration of the study (i.e., beginning 30 days prior to Baseline and extending to 30 days after the last dose of study drug). The two methods of preventing pregnancy should include:

i. One barrier method (e.g. diaphragm with spermicide, condom with spermicidal gel, cervical cap);

ii. One other highly effective method that could include hormonal contraceptives (e.g. combined oestrogen and progesterone containing, or progesterone only with oral, vaginal, injectable, or transdermal route of administration), intrauterine device, or intrauterine hormone releasing system used for at least 4 weeks prior to sexual intercourse;

Note: Vasectomised partner is a highly effective birth control method provided that the partner is the sole sexual partner of the WOCBP trial participant and that the vasectomised partner has received medical assessment of the surgical success of the vasectomy.

Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments. The withdrawal method is NOT a form of abstinence and only COMPLETE abstinence is highly effective. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the participant.

Currently, it is not possible to determine the efficacy of oral contraceptives as an effective method of preventing pregnancy for WOCBP who are participating in this study. Oral oestrogen and progestin hormonal contraceptives as a sole method of preventing pregnancy are therefore prohibited.

Except abstinence, no one method of preventing pregnancy is 100% effective. If you think you may have become pregnant even though you used correct preventing pregnancy method while in the study, you MUST contact the study doctor or the study staff immediately (see telephone number at the first page of this form).

If you are a female participating in this study and become pregnant tell your study doctor or study staff immediately. The study doctor will ask to review your medical records and the infant's medical records after delivery. The study doctor will share information about the pregnancy with the study sponsor to help understand the effects, if any, that the study drug may have on the pregnancy and the child.

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

If you become pregnant while you are participating in this study or within 30 days after you have stopped taking the study drug, tell your study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended.

Males:
To reduce the risk of pregnancy, fertile men (including those vasectomized for less than 6 months) with female partners who are WOCBP (not having undergone bilateral tubal

occlusion procedure and not post- menopausal) must agree to use highly effective birth control including two methods of preventing pregnancy, for the duration of the study and for 90 days after your last dose of the study drug.,

If you are a male participating in this study, you must avoid impregnating your female partner while you are participating in this study. The following are accepted methods of preventing pregnancy:

i. One barrier method (e.g. diaphragm with spermicide, condom with spermicidal gel, cervical cap);

ii. One other highly effective method that could include hormonal contraceptives (e.g. combined oestrogen and progesterone containing, or progesterone only with oral, vaginal, injectable, or transdermal route of administration), intrauterine device, or intrauterine hormone releasing system used for at least 4 weeks prior to sexual intercourse;

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

If your female partner becomes pregnant while you are participating in this study or within 90 days after you have stopped taking the study drug, tell your study doctor or study staff immediately. In that case, she will be provided with the separate "Information Sheet and Informed Consent Form for Collection of Data on Pregnancy and Birth (for Pregnant Partner)" document and will be asked to give permission for the collection of her medical information regarding her pregnancy as a follow-up to this clinical research study.

Diagnostic procedures

Some of the assessments performed during the study may have risks independent of the study medication.

- 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.
- Pharmacogenetic (PG) blood DNA sample collection: There are non-physical risks associated with taking part in PG sample collection, such as risks associated with loss of privacy and confidentiality. Although your study doctor and study team take measures to protect your privacy, it may be that your identity could become re-connected with your genetic and health information. If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks.
- 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.

Your study doctor will give you more details about possible symptoms before performing these tests. This is optional and voluntary. You and your partner can choose not to participate in this data collection activity with no effect to your health care benefits.

8. WHAT ARE THE EXPECTED BENEFITS OF PARTICIPATING IN THIS STUDY?

There may or may not be direct medical benefits to you from participating in this study. Your participation in this study will contribute to increasing information that may help treating patients with OCD and may contribute to improvements in medicine in general.

9. WHAT ARE THE TREATMENT ALTERNATIVES FOR THIS DISEASE?

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

- Non-medication treatment, such as exposure response prevention therapy or cognitive behavioural therapy
- Other medications for OCD including some antidepressants or antipsychotics

You can talk to your study doctor or GP about the available alternative treatments and their important potential benefits and risks before you decide whether you will take part in this study.

10. WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the clinical study new information becomes available about the drug that is being studied. If this happens, your study doctor will inform you about it in a timely manner and discuss with you whether you want to continue your participation in the study. If after receiving this information you decide to stop participating in the study, your study doctor will make arrangements for your care to be continued. If after learning of the new information you decide to continue participating in the study, you may be asked to read an updated Participant Information Sheet and sign an updated Informed Consent Form.

It is also possible that after receiving new information your study doctor decides to withdraw you from the study. If so, he/she will explain the reasons to you and arrange for your healthcare to be continued.

11. WHAT HAPPENS IF YOUR PARTICIPATION IN THE STUDY ENDS BEFORE STUDY COMPLETION OR IF THE CLINICAL STUDY IS PREMATURELY TERMINATED?

Your decision to take part in this study is voluntary. You may choose to not take part, or you may withdraw from the study without providing any reason. You will continue to receive all healthcare benefits with no effect. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study.
The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is cancelled by the regulatory authority, Biohaven Pharmaceuticals, Inc., or the IEC; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests (2-Week Post Dose Visit) for your safety.

12. WHAT IF SOMETHING GOES WRONG?

Before agreeing to take part in this study, you should consider if this will affect any medical insurance you have and seek advice if necessary. This is to ensure that your participation will not affect your medical insurance cover.

If you become ill or suffer any health impairment as a direct consequence of the appropriately dosed and administered treatment (as per instructions), or in conjunction with any of diagnostic examinations carried out exclusively for the purposes of the study, you will receive medical care for this health impairment. All costs of such medical care will be paid for by the sponsor through their mandatory insurance for this kind of issue. The contact details of the insurance company are:
Name: Armfield, Harrison & Thomas, LLC
Address: 458 South Ave.
Whitman, MA 02382
Number of Insurance policy: 36064415

In the event of serious health impairment that results in durable/persistent disability as a result of the study medication or the diagnostic procedures carried out for the purposes of the study, the sponsor undertakes to pay the compensation.

However, this agreement to provide free medical treatment does not include treatment for any illness you might get during the study that is not a direct result of participating in the study, including any medical condition that existed before the participation.
If you have a concern about any aspect of this study, you should speak with your study doctor or nurse. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. 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 (Patient Advice and Liaison Service, also known as PALS Tel: 01908 995954).

We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

We will pay compensation where the injury probably resulted from:

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

Any payment would be without legal commitment (please ask if you wish for more information on this).

We would not be bound by these guidelines to pay compensation where:

- The injury resulted from a drug or procedures outside the study protocol.
- The protocol was not followed, i.e., in case you did not follow the study requirements.

13. WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

What is patient data?
When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and

treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It's important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What sort of patient data does health and care research use?
There are lots of different types of health and care research.
If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won't need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher collects from the health records is research data.

Why does health and care research use information from patients?
In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient's health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

How does research use patient data?
If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

Where will my data go?

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses.

The bigger research team may include people who check the quality of the research. Regulators may also need to check the research. They will compare the recorded research data with your health records. They might read your health records through a secure internet connection or at the hospital or clinic. All the computers storing patient data must meet special security arrangements.

If you want to find out more about how companies develop and sell new medicines, the Association of the British Pharmaceutical Industry has information on its website.

What are my choices about my patient data?

- You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
- In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.
- Researchers need to manage your records in specific ways for the research to be reliable. This means that they won't be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

What happens to my research data after the study?

Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research.

Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

Will the use of my data meet GDPR rules?
GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

What if I don't want my patient data used for research?
You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine.

In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

1. When the research is using anonymous information. Because it's anonymous, the research team don't know whose data it is and can't ask you.
2. When it would not be possible for the research team to ask everyone. This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can find out more.

If you agree, your GP will be informed in writing about your participation in this study. This may include other medical doctors not involved in the clinical study who may be treating you.

Who can I contact if I have a complaint?
If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

Because the sponsor is located outside the UK, Accelsiors CRO and Consultancy Services (UK) Ltd. (20-22 Wenlock Road, N1 7GU, London, the UK) has been appointed to act as its representative. Sponsor's data protection representative email address: dataprotection@accelsiors.com.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Personal Data for Direct Shipment of Study Drug to Participants
Due to concerns related to the COVID-19 pandemic, you may be unable to come into the office for your scheduled study visit, in order to minimize any potential risks to your safety and to comply with governmental and local institutional guidance (for example, the study site has a policy that a clinical research visit must be delayed). Under these circumstances, you may also have the study drug mailed to your house and you will have to be home to sign for the package. In order to ship the study drug to your house the site personnel will need to enter your personal information into an electronic system, known as the Interactive Response Technology (IRT), for the study drug to be shipped. This personal information would include: your **full first and last name**, **your street address**, **city,** and **state**. Please note that only the drug depot that is shipping the study drug will have access to your information. The private information will otherwise be blinded to the sponsor and their designees. The drug depot will use the data only for the purpose of shipping the study drug and it will not be shared or stored beyond this task. IRT service provider is based out of UK. However, they must follow our rules about keeping your information safe.

Please indicate your decision to provide your personal information as noted above if coming into the clinic is not possible due to the COVID-19 pandemic, in the informed consent.

14. WHAT WILL HAPPEN TO THE RESULTS OF THE CLINICAL RESEARCH STUDY?

The data from all the participants participating in this study will be collected and analysed. Access to the data will be restricted to authorised personnel only who will respect the confidentiality of such information. These data will remain the property of Biohaven Pharmaceuticals, Inc.

A description of this clinical study (trial) will be posted on the UK Clinical Trials Registry (https://www.isrctn.com/) as required. 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. A description of this clinical study will also be available on http://www.ClinicalTrials.gov, as required by U.S. Law. The gender and age will be published in the study findings. But no one will be able to identify you from it.

The final results, i.e., the study outcome, will be filed in the dossier prepared for marketing authorization of troriluzole, and will be presented to Regulatory Authorities. With your identity always being kept confidential, the final results will be disclosed to the local Regulatory Authorities and Ethics Committees and will be submitted to an international medical journal.
If you stop participating in this study, you have the right to withdraw your authorization to disclose information. If you withdraw your authorization, your study doctor will not use or release any new information obtained after receiving your request. However, your study doctor and the Sponsor may continue to use information already obtained in order to maintain the integrity of the research study.

Research results that are clinically relevant, including individual research results, **will be disclosed to you** under these conditions: The information collected as part of this study is being obtained for research purposes only. The data are not being collected for clinical purposes and will not be provided to you unless there are clinically relevant findings that may be reviewed by a study doctor or provided to you to take to your GP.

15. WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been reviewed by the following Ethics Committee:

Name: North West - Greater Manchester South Research Ethics Committee

Address: 3rd Floor, Barlow House, 4 Minshull Street, Manchester M1 3DZ

under the following number:
Number: REC Reference: 21/NW/0137

An Ethics Committee is a group of people who review research studies. Their purpose is to protect the rights and welfare of research participants. Review and approval do not mean that there are no risks associated with your study participation.

16. CONTACT FOR FURTHER INFORMATION

If you need further information about participation in the study, your rights, or potential side effects, please call your study doctor:

Name of the study doctor: Dr Joshua Asubiaro
Phone No.: +441908 985540

If applicable
If you have questions about the study that you are not able to resolve with your study doctor or staff, you may contact the appointed person at PALS or the contact independent of the study to discuss your questions or complaints:

Name: Orsolya Lawrence

Phone: +441908 985540

17. FINANCIAL CONSIDERATIONS

No incentives or financial inducements are foreseen for your participation in this clinical study.

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided free of charge to you or your insurance company.

You will receive reasonable compensation of 70 pounds per visit for inconvenience and loss of time caused by participation in the study according to local legislation and site-specific procedures. Additionally, if you have travel related expenses or if some accommodation is to be arranged for any study visit (due to some study-related procedures), you will be reimbursed against receipts with prior approval, for the duration of the study. The duration of the study is from the screening to the final visit and any other unscheduled visits that may be required. If participants do not complete the study, they will be paid for their commitment to the study up to that point. Additionally, reimbursements may be made in accordance with the local legislation. The Sponsor will compensate the study doctor and study staff for the costs of performing this study.

Serious non-compliances (not following the instructions) with the protocol and study restrictions may result in participants' suspension from the study with compensation fully withheld.

18. BIOLOGICAL SAMPLES

All coded biological samples taken for study purposes will be analysed and processed at analytical laboratory(ies) (ACM Global Laboratories, 160 Elmgrove Park, Rochester, NY 14624). Biological samples may be retained at the analytical laboratory(ies) until the trial is completed and reported.

Your biological samples collected during this study will not be used for future research. The samples will be destroyed when analyses are completed and are final.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", the letters in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research might include whole genome sequencing.

Thank you for reading this information. If you want to take part in this study, please sign the Informed Consent Form and return it to your study doctor. You will be given a signed and dated original copy of this Participant Information Sheet and Informed Consent Form for your own records.