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:	*[Please enter]* Dr Muthukrishnan
Study centre Address:	*[Please enter]* Victoria Centre, 53 Downs Way, Great Western Hospital site, Swindon. SN3 6BW
Study-related phone number(s):	Phone Number: 01793 327954 Phone Number (24 hours): 07768 375908

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.