Salix Pharmaceuticals, Inc.
Advancing Treatment in Gastroenterology

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Summary Participant Information Sheet

Study Title: **Irritable Bowel Syndrome with Diarrhoea (IBS-D) Rifaximin Re-Treatment Study**

Sponsor: **Salix Pharmaceuticals, Inc.**

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important for you to understand why the research is being done and what it will involve. This information sheet gives a **brief summary** of the study. If, after reading it, you are interested in finding out more, you will be asked to read the full patient information sheet and sign a consent form. This must be done **before** any other study procedures are performed.

- The study will test a new drug for IBS-D by comparing it to a placebo (dummy drug with no active ingredient).
- Each participant's involvement in the study will last for up to 51 weeks. About 800 participants will enter from 3 different countries and around 250 different study centres.
- You do not have to take part in this study. It is up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time and without giving a reason.
- The new drug being tested is called rifaximin. Rifaximin is an antibiotic known to have an effect on gut bacteria. The drug is already available for use in the US and the UK under a different name for the treatment of Traveller's Diarrhoea (TD) and Hepatic Encephalopathy (HE).

The study is composed of the following:

- Screening/Treatment 1 Phase: may consist of 1 or 2 study visits. The entire phase may last up to 37 days. The treatment portion, in which you will take study medication, will be 7 to 13 days in duration.
- Treatment Phase 2: a 6 week period (2 weeks of treatment and 4 weeks follow-up)
- Maintenance Phase 1: a treatment-free period of up to18 weeks
- Treatment Phase 3: a 6 week period (2 weeks of treatment and 4 weeks follow-up)
- Maintenance Phase 2: a 6 week treatment-free period
- Treatment Phase 4: another 6 week period (2 weeks of treatment and 4 weeks follow-up)
- End of Study - Follow Up Phase: a 4 week follow-up period

- If you decide to take part in this study, the treatment you will be given will be decided in a random manner (similar to drawing numbers out of a hat) and at some point during the study, beyond Treatment 1, you will receive treatment with rifaximin for 2 weeks

- The design of this study is double-blind, which means that neither you nor your study doctor will know which treatment you are receiving, although if your study doctor really needs to find out he/she can do so

- The study drug will be taken orally (by mouth), as tablets, every day for 2 weeks for up to 4 treatment periods followed by periods where you will receive no treatment

- You will be expected to complete a study diary every day throughout your participation in the study, by answering questions relating to your IBS symptoms either over the phone or by accessing the internet

- It is possible that you may have some side-effects from the treatment that you take in this study, and these are explained in detail in the full participant information sheet. You will be monitored closely to check for any side-effects, and if necessary, you will be treated immediately

- You may or may not benefit from taking part in this study. We hope that the study treatment will help you. However, there is no guarantee of this

- If you decide to take part in this study, you will come to this clinic for your scheduled appointments. The tests you would need to have at some/all of these appointments include:

    - physical examination
    - blood pressure and heart rate
    - ECG (a test looking at the electrical activity of your heart)
    - blood, stool and urine samples
    - pregnancy testing (for women who can have children only)
    - IBS quality of life questionnaires

    - colonoscopy/flexible sigmoidoscopy-if you have not had one before or if your last one was more than 10 years ago

- At each visit your study doctor will want to know if you have noticed any side-effects or other symptoms since the last visit, and whether you have started taking any new medicines
- You will be reimbursed for any reasonable travel expenses incurred due to attendance at study appointments and for your study diary entries
- Compensation for any injury caused by taking part in this study will be provided in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI)
- If you have a complaint about something serious that happens to you as a result of taking part in this study you should contact your study doctor first
- If you consent to take part in this study, responsible individuals from the company sponsoring the research (Salix Pharmaceuticals, Inc.), their affiliated companies and responsible individuals from the company managing the research (TMC Pharma Services Ltd.) may look at sections of your medical notes, data and samples. However, nothing that could reveal your identity will be disclosed outside this research clinic
- The results of the study may be published in medical or scientific journals. If this happens, your identity will still remain confidential at all times
- Your study doctor will inform your GP about your involvement in this study if you consent to participate in this study
- The pharmaceutical company organising and funding this study is called Salix Pharmaceuticals, Inc. Salix Pharmaceuticals, Inc will pay some money to this clinic for including you in this study
- Before this study started, it was reviewed and approved by the North West-Greater Manchester Central Research Ethics Committee, an independent ethics committee

Contact details for further information

If you think you would like to take part in this study after reading this **summary** participant information sheet, please contact your study doctor or a member of the study team. He/she will be able to give you a copy of the full participant information sheet, and answer any questions that you might have. Their details are:

Study Doctor: Professor Peter Whorwell	0161 291 5813
Study Coordinator: Maggie Hastings	0161 291 4188 / 4190