SOTERIOS

Local site logo

PATIENT INFORMATION SHEET

A Double-Blind, Multicentre, Placebo controlled, Parallel group design to assess the Efficacy, Safety and Dose response characterisation of a Controlled release formulation of STS01 (Dithranol/Prosilic) for the treatment of Mild-Moderate Alopecia Areata (AA).

You are invited to participate in a research project called SOT01. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve.

Please read this information carefully, and discuss it with others if you wish. Ask us if anything is unclear, or if you would like more information.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

What is the purpose of the study?

Currently, there is no cure for Alopecia areata and no generally accepted proven therapy. Available treatments often come with side effects and are not very effective in re-growing hair. Dithranol has been used for many years as a treatment for psoriasis and research suggests it may also be an effective treatment for Alopecia areata. Its use as an Alopecia areata treatment has been hindered by the localised side effects the drug produces; users have sometimes complained of scalp irritation, staining of the skin and clothes, and an unpleasant odour.

We have produced a new form of the drug using a technology that our research shows promotes release more slowly over a period of a few hours. We expect that releasing dithranol in this way will reduce the likelihood of these side effects. This study is therefore being carried out to determine how effective the new dithranol formulation is in inducing hair regrowth as well as the extent of any side effects.

We would like to invite you to consider taking part in the study of this new formulation of a topical cream to treat Alopecia areata. We will compare our treatment against a placebo (dummy medicine) in order to establish if the new treatment is effective and removes the side effects.

Following an initial review and assessment of your condition you will be invited to take part. If you do not meet the criteria you will be followed up by your Dermatologist or GP Doctor in the usual manner. If you are eligible and agree to participate you would receive treatment on a daily basis for a period of 6 months and be followed up for a further 2 months. During this time you would be seen and assessed regularly every 2 months.

You will be asked to apply a small amount of the cream (sufficient to completely rub into the patch) every day. You may, of course, wash it off with soap and water if you become at all concerned of the effect.

Why have I been chosen?

You have an autoimmune condition called Alopecia areata that has led to patchy or partial hair loss on your scalp. To be included in the study you must have had your current episode of Alopecia areata for at least 6 months, be generally in good health and not planning to become pregnant. In addition, you should not be using any other alopecia treatments for at least 6 weeks (or 3 months depending on medication).

If you are receiving treatment but are willing to enter a 'washout' period of 6 weeks you may still be eligible to take part. A wash out period means that you would cease to use your current treatment for 6 weeks before starting this study.

There are a number of other associated medical conditions, prohibited medications and general exclusions, such as unstable thyroid conditions, allergy to soya bean or peanuts or taking other experimental clinical trial drugs for 3 months but these will be checked through with your doctor to ensure it is safe for you to take part.

As the treatment under investigation is intended for people with mild to moderate Alopecia areata affecting the scalp people with hair loss extending to other bodily areas, such as the eyebrows or beard will, unfortunately, not be able to participate.

Do I have to take part?

No, participation is entirely voluntary. If you do decide to take part you will be asked to sign a consent form and you are free to withdraw at any time and without giving a reason. If you do not decide to take part, your Doctor will be happy to explain how they will manage your condition as part of routine clinical practice. You don't have to give a reason for not taking part and your standard of treatment and care will not be affected.

What will happen to me if I take part and what study procedures and tests will be involved?

The best way of finding out if there are any advantages or disadvantages to this treatment is by conducting a randomised study. 'Randomised' means that patients will be allocated a particular dose strength of the new dithranol formulation, or a placebo by chance. There is a 1 in 5 chance you may receive the placebo in this study. Neither you nor your doctor will choose which treatment you get.

This is also a 'double blind' study; this means that neither you nor your Doctor will know which treatment you have been allocated as all the cream forms look identical.

We will also send a letter to your GP (with permission) to let them know you are taking part in the study. Your GP will also not know what treatment has been allocated.

You be will assessed to establish if you are suitable for treatment. A member of the team will explain how to apply the cream product, and answer any questions that you may have. From start to finish your involvement in the study will last for 8 months. The treatment period is 6 months with a 2 month follow up check.

The assessments will be completed at a Screening appointment visit to assess eligibility. These will then be repeated at the beginning of the treatment to provide a baseline. During the study tests of

efficacy and safety will be carried out after 2, 4, 6 months of treatment and after a further 2 months at follow up. The tests are quick, simple and very similar to those routinely carried out at your clinic.

The assessments performed are:

- Simple visual inspection of the scalp to determine the extent of hair loss (Severity of Alopecia Test (SALT) score)
- High definition photographs of the scalp to assess the state of hair growth and also score hair loss (SALT score).
- Blood tests for routine safety and assessment of the alopecia condition
- Brief physical examinations, an ECG and Vital signs for safety

We will also ask you to

- Complete questionnaires on your health, hair growth and quality of life

What is involved in the study?

At the first Screening visit, if you are suitable to take part, basic demographic details, medical history and any previous medication will be recorded together with a blood test and a short physical examination with an ECG and vital signs. Photographs of your scalp will also be taken for evaluation.

At the second visit some of these tests will be repeated to provide a baseline. You will be randomised to a specific treatment and receive the first tube of medication. You will also be asked what other medication you may currently be taking.

At three subsequent visits during the course of treatment (2, 4, 6 months) photographs of the scalp will be repeated and vital signs checked. You will be asked if you need another tube of test cream to apply and what other medication you may have taken.

In addition, at the end of the 6 months treatment the physical examination performed at screening will be repeated.

Following this treatment period the Doctor will also ask you to return 2 months later after stopping treatment to see if there have been any changes. Photographs of your scalp will also be taken one last time as well as a blood test and a short physical examination with vital signs.

At each visit you will be asked (if applicable) to provide a urine sample to confirm you aren't pregnant.

The Doctor will also assess your condition at the start of treatment and again at the end.

How long will I be involved in the study?

Your total involvement is 8 months. You will receive study medication for 6 months and also attend a follow up visit for a check-up 2 months later

Additional visits are possible and may be requested, but only in the very unlikely event of a side effect which is believed to be serious.

While on treatment we will monitor your progress closely. Doing so will give us information about the best ways to develop this type of treatment in the future. There are some circumstances when

we might consider it in your best interests to stop your participation in the study, for example if we feel that the treatment is doing harm or if your condition worsens. If so, we will explain the reasons to you and arrange for your care to continue.

What are the alternative treatments?

There are no regulatory approved treatments for Alopecia areata either in the UK, USA or indeed worldwide. In fact the US regulatory authorities, the FDA, have identified this condition as an area of major unmet need for patients, particularly because of the distressing nature of the condition.

Harm to an unborn child?

There is no evidence that the treatment causes harm either to the breast feeding mother, infant or unborn child. However we ask that all females participating in the study should be taking adequate contraceptive to prevent pregnancy for the duration of treatment. The specific details will be discussed with the Doctor.

Obviously you should tell the Doctor if concerned that you may have become pregnant during the course of treatment.

What are the possible disadvantages and risks of taking part?

We do not perceive any risks to taking part as the drug dithranol has been shown to be safe for many years with reports only of minor scalp irritation and skin staining. It is currently already being used to treat the condition by some Doctors. However, involvement requires time and commitment to follow the regimen of therapy and attend follow up visits and this may be considered a disadvantage and inconvenience. The Doctors involved are very appreciative and grateful for this effort.

What are the possible benefits of taking part?

The information gained may help Doctors offer a proven therapy for your condition in the future.

If this study is successful it will firstly lead to another larger trial (called Phase III) which is necessary for any medical drug to be licensed for general use.

Complaints:

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal local complaints service are available to you.

PALS [Or insert local complaints department] **Tel:** [Insert local phone number]

What will happen if I don't want to continue in the study?

You are free to withdraw at any time and without giving a reason. However, with your permission, we will utilise any data that has already been collected.

Should you decide not to carry on you would continue attending appointments with your Dermatologist and/or GP as part of your standard care.

What if new information becomes available?

It is very unlikely that new information will become available. However, if this happens, we will tell you and ask you if you wish to continue. If you decide to leave your standard care will not be affected. If you stay you may be asked to sign a new consent form.

Who is organising and funding the research?

This research is sponsored by a UK company called Soterios Ltd. They have overall responsibility for the conduct and management of the study

What happens if I am injured because I took part in this study?

The Association of the British Pharmaceutical Industry (ABPI) guidelines relating to study induced injury recommend that "the sponsor", without legal commitment, should compensate you in accordance with the terms of such guidelines without you having to prove that it is at fault. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study, which you otherwise would not have had. The Sponsor will not compensate you where such injury results, for example, from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected.

You can get a copy of the guidelines from your hospital or write to:

ABPI head office, 7th floor, southside, 105 Victoria Street, London SW1E 6QT Tel: +44 (0)20 7930 3477 or visit:

http://www.abpi.org.uk/contact-us/

If you have a concern about any aspect of the study, you should speak to your research doctors or nurses who will do their best to answer your questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanism will be available to you. Details can be obtained from the Patient Advice and Liaison Service at your hospital.

PALS Contact Details:

{Enter contact details/open hours}

{Email}

{Postal Address}

Will my taking part in this study be kept confidential?

Your participation in the study will be kept completely confidential. Your identifying details will only be recorded in your personal medical records at the hospital and your GP informed (if you so wish).

In addition, the data you provide for evaluation of the treatment will be completely anonymised and it will be impossible to identify you from this information.

Processing of your personal information in this clinical research study

This section explains how we process (e.g. collect, use, store, and share) your personal information. We will process any personal information about you in accordance with this section, with the GDPR, and with applicable law in the United Kingdom.

Who are We?

Soterios Ltd. is the Sponsor for this study. Our headquarters are located in the United Kingdom. We will be using personal information about you that we might obtain from you, your medical records, and your healthcare professional in order to undertake the study. Details about the study, including what is expected of you, and the type of information we will obtain are given elsewhere in this Patient Information Sheet.

Soterios Ltd. will be the data controller for the study. This means that we are responsible for looking after your personal information and using it properly and only for the reasons described in this Patient Information Sheet.

If you have any questions or concerns about how we use your personal information, you can contact our Data Protection Officer by emailing davidfleet@manentia.co.uk or calling 07533002238

Why Do We Collect Your Personal Information?

We will use your personal information solely for the purposes of conducting the study and analysing the results, and in order to understand the effects of the treatment(s) under investigation.

How Do We Collect Your Personal Information?

Your healthcare provider will collect your personal information and provide it to us on paper documents or in digital format. If the study requires it, your blood samples may be sent to a laboratory for testing and the results of those tests will be sent to your healthcare provider and/or directly to us or someone acting on our behalf.

What Type of Personal Information Will We Collect from You?

The type of personal information we will collect is given in this Patient Information Sheet. Please read this carefully and make sure you understand it and have had the opportunity to ask your healthcare provider any questions. Only your healthcare provider will keep your name, contact details, and any other information that may directly identify you (for example, a hospital number). This information will not be passed to us or someone acting on our behalf. However, your healthcare provider will use this information as needed, for example, to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the Sponsor (or another organisation acting on our behalf), or regulatory organisations may look at your medical and research records to check the accuracy of the research study. We will only receive your personal information identified by a study code that cannot be traced back to you except by your healthcare provider. This is called 'pseudonymisation' and the people who review or analyse your personal information will not be able to identify you.

What is the Lawful Basis that Allows Us to Process your Personal Information?

As a pharmaceutical company, we have a legitimate interest in processing your personal information. We are also required by law to process your information when you participate in clinical research sponsored by us.

We are always seen to maintain a balance between our legitimate interests and your privacy.

How Do We Share Your Personal Information?

In the course of our activities and for the same purposes as those listed in this Patient Information Sheet, your personal information can be accessed by, or transferred to the following categories of recipients on a need-to-know basis:

- our personnel (including personnel, departments or other companies of the Soterios group);
- our contract research organisations and contract laboratories;
- our IT systems providers, cloud service providers, database providers and consultants;

These other parties are contractually obliged to protect the confidentiality and security of your personal information in compliance with applicable law.

Your personal information can also be accessed by or transferred to any national and/or international regulatory, enforcement, public body or court, where we are required to do so by applicable law or regulation, or at their request.

What Happens if We Transfer Your Personal Information Outside the UK/EEA?

Your personal information may be transferred and processed in a country outside the UK/EEA where personal information protection laws may be different to the UK/EEA. We will ensure that the privacy and confidentiality of your information is protected according to the same standards and requirements of GDPR and the information protection laws in your country.

If your personal information is transferred and processed outside the UK/EEA it will always be coded so that you cannot be identified directly. The information will only be used for the purpose of clinical research and cannot be used to contact you or to affect your care.

How Long Will We Keep Your Personal Information?

We will only retain your personal information for as long as necessary to fulfil the purpose for which it was collected or to comply with legal or regulatory requirements. Normally, the minimum legal requirement for clinical research is 25 years.

What are Your Rights?

You have certain rights as follows:

- You can ask us to confirm that we are processing your personal information, and to request access to that personal information. However, since your personal information is coded, we cannot link the information back to you, so it is better to ask your healthcare provider for access first.
- You may also request that we ensure the accuracy and amend any inaccurate information. Again, since we cannot link the information back to you, it is best to ask your healthcare provider first.

- You may also ask for a restriction on processing or object to the processing of your personal information. However, should you withdraw your consent to future processing of your personal information; this could make it impossible for you to continue in the study. In addition, although you have the right to withdraw your consent at any time, this will not affect the lawfulness of processing of your personal information before the withdrawal.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you wish to exercise any of your rights as an information subject, please contact your healthcare provider in the first instance as this will ensure your request will be dealt with efficiently and your identity does not need to be revealed to us as the Sponsor.

You also have the right to complain about the collection, processing, use, and disclosure of your personal information to a Supervisory Authority. The Supervisory Authority in the UK is the Information Commissioner's Office (ICO) their contact details can be found at https://ico.org.uk/.

Contacting your GP

It is standard practice for your GP to be told if you are taking part in research. With your consent, your GP will be informed that you are taking part in this study.

What will happen to the results of the research study?

The results of the study will be available after the data analysis is complete. We will present the data at National and International meetings. Furthermore, we will aim to publish the data in a peer-reviewed medical journal. You will not be identified in any report or publication. At the conclusion of the study all participants will be provided with a clear, non-technical summary of the results.

What happens when the research study ends?

After completion of the study, your progress will be assessed by your consultant, if you have one, and a new treatment regime suitable for you will be selected. You will not be able to continue on the study drug as it is not currently available for use outside of the trial.

Who has reviewed and checked the study?

The Medicines and Healthcare products Regulatory Agency (MHRA) has approved the use of the new formulation of dithranol for this clinical study.

All research at the study centre is also reviewed by an independent group of people called a Research Ethics Committee, who work to protect your safety, rights and wellbeing. The study has been reviewed and approved by the Research Ethics Committee. In addition, the Research Ethics Committee will observe the progress and results of this study. The suitability of hospital / study centre to carry out this study also has been assessed by the Sponsor. Your hospital has also reviewed

and approved the study and the study was reviewed by independent experts during its development.

This patient information sheet was also reviewed by an independent patient and public involvement panel to ensure sufficient information has been provided to you.

Travelling Expenses

Travelling expenses are available if required.

Who do I call if I have questions or problems?

CONTACT TELEPHONE NUMBERS:

If at any time you are concerned or require additional information, please contact [Dr XXX], the Chief Investigator for the study:

<<Insert Dr's contact information here>>

Tel: <<insert local number>>

Or <<Dr example>>, the local Principal Investigator of the study:

<<Insert Dr's contact information here>>

Tel: <<insert local number>>

Research Nurse <<Insert Research Nurse information here>>

Tel: <<insert local number>>

If you feel unwell after your treatment:

If you are concerned about any problems please ring the hospital hotline.

The Hotline is open 24 hours a day. Do not delay your call.

Contact Name /Tel: <Contact/Number>

Where can I get more information?

If you wish to discuss this study and your rights as a research subject with an independent person then please contact the person below, who is not directly involved in the study, but will be happy to discuss any issues you have.

Contact PALS on <Enter No.>.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION