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Study Title:
A Phase II Study to Assess the Efficacy and Safety of Dermalexiin (DLX-412) Cream in Adults with Moderate-to-Severe Atopic Dermatitis

IRAS ID: 000000 (Fictional)

Protocol Number: DERM-001

Sponsor: MolendiiP Pharma Ltd

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PART 1 – What you need to know before deciding

Invitation to take part in a research study

You are being invited to take part in a clinical research study. Before you decide whether to take part, it's important you understand why the study is being done and what it will involve.

Please take the time to read the following information carefully. You are welcome to ask us questions and discuss them with friends, family, or your GP.

Participation is entirely voluntary. Your usual medical care will not be affected if you decide not to participate.

1. What is the purpose of the study?

This study is testing a new cream called **Dermalexiin (DLX-412)** to see whether it improves the symptoms of moderate-to-severe eczema (also known as atopic dermatitis). We also want to understand how well it is tolerated and whether there are any side effects.

Eczema can cause dryness, redness, itching, and irritation. While some treatments are available, not everyone responds well. This study aims to find out whether Dermalexiin can improve symptoms over 12 weeks.

We plan to involve 100 adults across 4 centres in the UK.

2. Why have I been invited?

You are being invited because you have moderate-to-severe atopic dermatitis, and you are aged between 18 and 65 years.

3. Do I have to take part?

No. Taking part is entirely your choice. If you decide not to take part, it will not affect the standard of care you receive. If you choose to take part but later change your mind, you can withdraw anytime without giving a reason.

4. What will happen if I take part?

If you agree to take part, you will be asked to sign a consent form and attend a screening visit. If you are eligible, you will be randomly assigned (like tossing a coin) to one of two groups:

- One group will apply **Dermalexiin 5% cream**
- The other group will apply a **placebo cream** (which looks the same but has no active ingredient)

You will apply the cream once daily for 12 weeks. You will attend clinic visits at:

- Week 0 (screening/baseline)

- Week 2
- Week 4
- Week 8
- Week 12 (end of treatment)
- Week 16 (follow-up)

At each visit, we will assess your skin, ask questions about symptoms and side effects, and take photographs (if you consent).

PART 2 – More detailed information about the research

5. What are the possible benefits of taking part?

Taking part in this study may help improve your eczema symptoms, but we cannot guarantee any direct benefit to you. The information we learn may help improve treatment for others with eczema in the future.

6. What are the possible risks or side effects?

Dermalexiin is a new investigational cream. In earlier studies, most participants tolerated it well. However, as with any topical product, there may be side effects, including:

- Mild redness or irritation at the application site
- Itching or burning sensation
- Rarely, allergic skin reactions

If you experience any side effects, we will monitor them carefully and offer appropriate advice or treatment. You are free to stop treatment at any time if you are uncomfortable.

7. Expenses and payments

You will not be paid to take part in the study. However, we will reimburse you for reasonable travel expenses for clinic visits.

8. What if something goes wrong?

If you are harmed as a result of taking part in the study, MolendiiP Pharma Ltd has insurance in place to cover any study-related injury. You should contact the study team or your local NHS complaints procedure in case of a complaint.

9. Will my taking part in the study be kept confidential?

Yes. All information collected about you during the study will be handled in strict confidence, in accordance with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

You will be assigned a unique study number, and your name will not appear in published results. Your data will be securely stored and accessed only by authorised staff, study monitors, or regulators when necessary.

10. What will happen to the results of the research study?

The results of this study may be published in scientific journals or presented at conferences. You will not be personally identified in any report. If you would like a summary of the final results, you may request this from the study team.

11. Who is organising and funding the study?

This study is being organised and funded by **MolendiiP Pharma Ltd**, a fictional pharmaceutical company developing treatments for dermatological conditions.

12. Who has reviewed the study?

This study has been reviewed and approved by a **Research Ethics Committee** and the appropriate **UK regulatory authority (MHRA)** to ensure it meets ethical and scientific standards.

13. Contact for further information

If you have any questions or concerns about the study, please contact:

Study Doctor: Dr Jane Morgan

Study Site: Dermal Research Unit, East London Trust

Email: dermalexiintrial@fakemail.co.uk

Phone: 0123 456 7890

Thank you for considering taking part in this research.

Note:

This sample Participant Information Sheet has been created for educational and demonstration purposes only. Sections such as "What if new information *becomes available?", "Data Controller", and "How long will my data be kept?"* have been summarised or omitted for brevity. In a real clinical trial, these sections would be required in accordance with UK GDPR and HRA guidance.

Disclaimer:

This document is fictional and has not been reviewed or approved by any ethics committee or regulatory authority. The study, product (Dermalexiin), and sponsor (MolendiiP Pharma Ltd) are fictitious. This sample was created as part of a learning exercise in regulatory medical writing and should not be used for actual research purposes.