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Informed Consent Form for Clinical Trial Participants

This Informed Consent Form is for adult male and female patients diagnosed with moderate-to-severe atopic dermatitis who attend the Dermaclinic Research Centre in London and are invited to participate in a clinical research study. The title of our research project is:

"A Phase II, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Dermalexin in Adults with Moderate-to-Severe Atopic Dermatitis"

Principal Investigator: Dr Jamie Taylor

Organisation (Clinical Site): Dermaclinic Research Centre, London

Sponsor: MolerDiiP Pharma Ltd

Protocol Title and Version:

Protocol No. MDP-2025-AD02

Version 1.0 | Date: 24 April 2025

This Informed Consent Form has two parts:

- Part I: Information Sheet (to share information about the research with you)
- Part II: Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the complete Informed Consent Form to keep.

PART I: Information Sheet

Introduction

You are being invited to take part in a clinical research study. This form provides information about the study, including its purpose, procedures, risks, and your rights as a participant. Please take time to read it carefully and ask questions now or later. Your participation is entirely voluntary.

Purpose of the Research

This study is designed to test a new topical cream developed by MolendiiP Pharma Ltd., Dermalexiin. The research aims to evaluate whether this investigational treatment is safe and effective for people with moderate-to-severe atopic dermatitis.

Type of Research Intervention

This research involves the use of a topical investigational medicinal product applied to the skin, administered over a 12-week period, and compared with a placebo.

Participant Selection

You have been invited to participate because you are diagnosed with moderate-to-severe atopic dermatitis and meet the study criteria. We are inviting adults who attend the Dermaclinic Research Centre and are eligible under the study protocol.

Voluntary Participation

Participation is your choice. If you decide not to take part, you will continue receiving standard care for atopic dermatitis at this clinic. You can change your mind and withdraw at any time.

Information on the Trial Drug

Dermalexiin is being studied in this Phase II trial to assess its effectiveness and safety. MolendiiP Pharma Ltd. Known side effects produce it may include redness or irritation at the application site. Some participants will receive Dermalexin, while others will receive a placebo. Neither you nor your doctor will know which treatment you receive during the study.

Procedures and Protocol

Participants will attend six clinic visits over 12 weeks. We will collect blood samples at the first visit, review your medical history, and perform a skin assessment. You will be randomly assigned to receive either Dermalexin or a placebo cream. All creams look the same. You will apply the cream daily as instructed. Subsequent visits will include physical exams, symptom questionnaires, and monitoring for side effects. Any remaining samples will be destroyed at the end of the study.

Duration

Your participation will last 12 weeks. During this period, you will attend 6 scheduled visits, each lasting approximately 60–90 minutes.

Side Effects

You may experience mild skin reactions like redness, stinging, or itching. Other unexpected reactions are possible. You will be closely monitored and receive medical attention if needed.

Risks

While the risks are low, Dermalexiin may not work or cause discomfort. We will provide medical care will be provided if adverse events occur, and the sponsor will cover all study-related treatments.

Benefits

Although this is not guaranteed, you may experience improvement in your skin symptoms. Your participation will help advance medical knowledge and future treatment options.

Reimbursements

You will receive £25 per visit to cover travel and time. No other payment or incentive is offered.

Confidentiality

Your personal information will be kept confidential and coded with a unique ID. Only authorised study team members, ethics committees, or regulatory authorities may access this information.

Sharing the Results

The study's results will be shared through scientific journals and medical conferences. Once the study ends, you will be informed of the outcome, and no personal information will be disclosed.

Right to Refuse or Withdraw

You may withdraw at any time without affecting your future care. Participation is voluntary and entirely your choice.

Alternatives to Participating

If you choose not to participate, you will continue receiving the standard care provided by the clinic for managing atopic dermatitis.

Who to Contact

If you have questions about the study, please contact:

Dr Jamie Taylor

Dermaclinic Research Centre, London

 Email: dermaclinicresearch@aol.com

 Phone: +44 20 7946 246434

This study has been reviewed and approved by the London Regional Ethics Committee.

PART II: Certificate of Consent

(This is to be completed if the participant has agreed to participate in the study after reading or hearing the Information Sheet.)

Statement by the Participant

I have read the information provided (or it has been read to me). I have had the opportunity to ask questions about the study, which have been answered satisfactorily. I understand that participating in this study is voluntary, and I am free to withdraw at any time without giving a reason or affecting my medical care.

I voluntarily agree to participate in this study, which involves the investigational use of Dermalexiin as described in the information provided.

I understand that I will be given a signed copy of this informed consent form to keep.

Full Name of Participant: _____

Signature of Participant: _____

Date (dd/mm/yyyy): _____

If participant is illiterate:

A literate witness must sign below. The participant should choose the witness and must not be a research team member.

I have witnessed the participant's consent form being accurately read. The individual has had the opportunity to ask questions. I confirm that they freely gave their consent to participate.

Name of Witness: _____

Signature of Witness: _____

Date (dd/mm/yyyy): _____

Thumbprint of Participant (if applicable):

Statement by the Person Obtaining Consent

I have accurately explained the study to the potential participants and answered their questions. I confirm that the participant was not pressured in any way and that the consent was given freely and voluntarily.

I confirm that the participant has received a copy of this consent form.

Name of Researcher / Study Team Member: _____

Signature of Researcher / Study Team Member: _____

Date (dd/mm/yyyy): _____