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Clinical Study Report for Dermalexiin DLX-412

Study Title:

A Randomised, Double-Blind, Placebo-Controlled Phase II Study to Evaluate the Efficacy and Safety of Dermalexin (DLX-412) in Adults with Moderate-to-Severe Atopic Dermatitis

Protocol Number: DERM-001

Investigational Product: Dermalexin 5% Cream

Sponsor: MolendiiP Pharma Ltd

Study Phase: Phase II

Study Period: January 2024 – March 2025

Report Version: 1.0

Date: 26 April 2025

Declaration of Responsibility

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We, the undersigned, declare that:

- This Clinical Study Report (CSR) accurately describes the study's conduct, analyses, and results as specified in the protocol.
- The study was performed in accordance with the principles of Good Clinical Practice (GCP), the Declaration of Helsinki, applicable regulatory requirements, and the study protocol.
- All relevant data have been accurately reported, and no attempts have been made to conceal or misrepresent study findings.
- Any deviations from the original protocol have been described and explained within this report.
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Name Title Signature Date

(Sponsor Representative)

_____ _____ _____ _____

(Principal Investigator /Site Representative)

_____ _____ _____ _____

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List of Abbreviations

Abbreviation	Definition
AE	Adverse Event
CSR	Clinical Study Report
DLQI	Dermatology Life Quality Index
EASI	Eczema Area and Severity Index
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PI	Principal Investigator
SAE	Serious Adverse Event

Statement of Compliance

This study was conducted by the principles of the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6(R2) Guidelines, and applicable local regulatory requirements.

Synopsis

This Phase II, randomised, double-blind, placebo-controlled study evaluated the efficacy, safety, and tolerability of Dermalexiin (DLX-412) in adults with moderate-to-severe atopic dermatitis. A total of 100 participants were randomised in a 1:1 ratio to receive either Dermalexiin 5% cream or placebo, applied once daily for 12 weeks, across four (4) investigational sites in the United Kingdom. The study was conducted between January 2024 and March 2025.

The primary endpoint was the mean percentage change from baseline in the Eczema Area and Severity Index (EASI) score at Week 12. Secondary endpoints included changes in pruritus severity, Dermatology Life Quality Index (DLQI) scores, and the incidence of treatment-emergent adverse events.

Dermalexiin demonstrated a statistically significant improvement in EASI scores compared to placebo (mean change –65% vs –35%; p=0.021). Improvements were also observed in pruritus severity and DLQI scores in the Dermalexin group. No new safety concerns were identified, and no treatment-related serious adverse events occurred during the study.

1. Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterised by eczematous lesions, pruritus, and impaired skin barrier function. It significantly impacts patients' quality of life, often resulting in sleep disturbances, psychological distress, and social impairment. Despite the availability of existing therapies such as topical corticosteroids, calcineurin inhibitors, and systemic immunomodulators, many patients with moderate-to-severe AD experience inadequate symptom control or encounter unacceptable adverse effects.

A substantial unmet medical need remains for novel therapeutic options that provide effective symptom management while minimising systemic exposure and long-term risks.

Dermalexiin (DLX-412) is a novel cytokine-modulating agent formulated for topical administration. It is designed to target key inflammatory pathways implicated in the pathogenesis of atopic dermatitis, particularly the interleukin-4 (IL-4) and interleukin-13 (IL-13) signalling cascades. Dermalexin aims to offer effective disease control with an improved safety profile by achieving a predominantly local effect with minimal systemic absorption.

This Phase II study was conducted to evaluate the efficacy, safety, and tolerability of Dermalexiin 5% cream compared to placebo when administered once daily for 12 weeks in adults with moderate-to-severe atopic dermatitis. The study's primary objective was to assess the improvement in disease severity, as measured by the Eczema Area and Severity Index (EASI). Secondary objectives included evaluating pruritus severity, improving quality of life using the Dermatology Life Quality Index (DLQI), and determining safety outcomes, including adverse event incidence.

The study was conducted in compliance with Good Clinical Practice (GCP) guidelines, the principles of the Declaration of Helsinki, and applicable national and international regulatory requirements.

2. Study Objectives

2.1 Primary Objective

The primary objective of this study was to evaluate the efficacy of Dermalexin (DLX-412) compared to placebo in adults with moderate-to-severe atopic dermatitis, as measured by the mean percentage change from baseline in the Eczema Area and Severity Index (EASI) score after 12 weeks of treatment.

2.2 Secondary Objectives

The secondary objectives were to:

Assess the safety and tolerability of Dermalexiin during the 12-week treatment period.

Evaluate the effect of Dermalexin on patient-reported pruritus severity using a validated numeric rating scale.

Assess Dermalexiin's impact on health-related quality of life, measured using the Dermatology Life Quality Index (DLQI).

3. Investigational Plan

3.1 Study Design

The study was a Phase II, randomised, double-blind, placebo-controlled, multicentre clinical study designed to evaluate the efficacy, safety, and tolerability of Dermalexiin (DLX-412) in adults with moderate-to-severe atopic dermatitis. Participants were randomised in a 1:1 ratio to receive either Dermalexiin 5% cream or a matching placebo cream. Study treatments were administered once daily for 12 weeks, followed by a 4-week safety follow-up period.

The study was conducted in compliance with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, the Declaration of Helsinki, and all applicable national regulatory requirements.

3.2 Study Setting

The study was conducted at four investigational sites located within the United Kingdom. Site selection was based on the investigators' experience with dermatology clinical trials, their access to the target patient population, and their ability to conduct the study according to the protocol and GCP standards.

3.3 Study Treatments

Participants who were randomised to the active treatment arm received a 5% cream of Dermalexiin, which was applied topically to affected areas once daily. Participants in the control arm received a matching placebo cream, also applied once daily. To maintain blinding, the investigational product and placebo were identical in appearance, packaging, and labelling.

Participants were instructed on proper application techniques, and compliance was monitored throughout the study via participant diaries and returned medication counts.

3.4 Randomisation and Blinding

Randomisation was performed centrally using an interactive web response system (IWRS) to ensure allocation concealment. Randomisation was stratified by baseline disease severity (EASI score) to ensure balance between treatment groups.

The study was conducted double-blind. Participants, investigators, study personnel involved in clinical assessments, and sponsor representatives responsible for data analysis remained blinded to treatment assignments until the study was completed and the database locked.

Unblinding procedures were clearly outlined in the protocol and were only permitted in cases where knowledge of the treatment assignment was essential for managing a serious adverse event.

4. Study Population

4.1 Participant Disposition

A total of 120 individuals were screened for eligibility in the study. Of these, 100 participants met all inclusion criteria and were randomised in a 1:1 ratio to receive either Dermalexiin 5% cream or placebo cream.

Ninety-six (96) participants completed the study as per protocol: 48 participants in the Dermalexiin group and 48 in the placebo group. Four participants withdrew early from the study: two due to adverse events (one from each treatment group) and two due to loss to follow-up.

4.2 Demographics and Baseline Characteristics

The mean age of the randomised participants was 35 (range: 18–65). Female participants comprised 52% of the study population.

The mean baseline Eczema Area and Severity Index (EASI) score was 18.2, indicating moderate-to-severe disease severity across the study cohort.

Demographic and baseline disease characteristics were comparable between the Dermalexiin and placebo treatment groups, indicating successful randomisation.

5. Efficacy Evaluation

5.1 Primary Endpoint

The primary efficacy endpoint was the mean percentage change from baseline in EASI score at Week 12.

Participants treated with Dermalexiin demonstrated a statistically significantly greater reduction in EASI scores than placebo participants.

- Dermalexiin group: –65% mean change from baseline
- Placebo group: –35% mean change from baseline

The difference between groups was statistically significant, with a p-value of 0.021, based on an analysis of covariance (ANCOVA) model adjusting for baseline EASI scores.

5.2 Secondary Endpoints

Secondary efficacy analyses demonstrated:

- A greater improvement in pruritus severity, as measured by the numeric rating scale (NRS), in the Dermalexiin group compared with the placebo group (mean change –4.2 vs –2.1 points; p=0.034).
- A greater improvement in Dermatology Life Quality Index (DLQI) scores in the Dermalexiin group compared with the placebo group (mean change –6.1 vs –3.4 points; p=0.045).

These secondary outcomes support the primary efficacy findings, suggesting a clinically meaningful benefit of Dermalexiin treatment over placebo.

6. Safety Evaluation

6.1 Adverse Events

The overall incidence of adverse events (AEs) was comparable between treatment groups. In the Dermalexiin group, 20% of participants reported at least one adverse event, compared to 18% in the placebo group.

Mild application site reactions, including erythema and pruritus, were the most commonly reported adverse events in both treatment groups. These events were generally self-limiting and did not require discontinuation of study treatment.

No treatment-related serious adverse events (SAEs) were reported during the study, and no deaths or unexpected safety signals were identified in either treatment group.

All adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA), and severity was graded according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

6.2 Laboratory Evaluations

No clinically meaningful changes in laboratory safety parameters, including haematology, biochemistry, and urinalysis, were observed during the study period. Laboratory values remained within normal limits for most participants, and no laboratory abnormalities led to study withdrawal or treatment discontinuation.

7. Discussion and Overall Conclusions

7.1 Discussion

The Phase II, randomised, double-blind, placebo-controlled study evaluated the efficacy, safety, and tolerability of Dermalexiin (DLX-412) in adults with moderate-to-severe atopic dermatitis over a 12-week treatment period.

The study met its primary objective, demonstrating a statistically significant greater mean percentage reduction in Eczema Area and Severity Index (EASI) scores in the Dermalexiin group compared with the placebo group at Week 12 (–65% vs –35%; p=0.021). Improvements in secondary efficacy measures, including pruritus severity and Dermatology Life Quality Index (DLQI) scores, further supported the clinical benefit of Dermalexin.

Dermalexiin was generally well tolerated, with a safety profile comparable to placebo. The most commonly reported adverse events were mild, localised application site reactions and no treatment-related serious adverse events or deaths were reported. No clinically meaningful changes were observed in laboratory safety parameters.

The study's findings suggest that Dermalexiin may provide an effective and well-tolerated topical treatment option for patients with moderate-to-severe atopic dermatitis. However, interpretation of these results should consider certain limitations, including the relatively short treatment and follow-up periods and the modest sample size typical of Phase II studies.

Further investigation in larger, longer-term Phase III studies will be necessary to confirm these findings, evaluate long-term safety, and fully establish Dermalexiin's clinical utility.

7.2 Overall Conclusions

Dermalexiin 5% cream demonstrated statistically significant improvements in disease severity, pruritus, and quality of life measures compared to

placebo after 12 weeks of treatment in adults with moderate-to-severe atopic dermatitis.

Dermalexiin's safety profile was favourable, with no new or unexpected safety signals identified. Based on the results of this Phase II study, Dermalexiin warrants further clinical development in Phase III trials.

8. References

1. International Council for Harmonisation (ICH). E6(R2) Guideline for Good Clinical Practice. 2016.
2. International Council for Harmonisation (ICH). E3 Guideline: Structure and Content of Clinical Study Reports. 1995.
3. European Medicines Agency (EMA). Guideline for Good Clinical Practice. 2021.
4. World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 2013.
5. Hanifin JM, Rajka G. Diagnostic features of atopic dermatitis. *Acta Derm Venereol Suppl (Stockh)*. 1980;92:44–47.
6. Weidinger S, Novak N. Atopic dermatitis. *Lancet*. 2016;387(10023):1109–1122.
7. Hanifin JM, Thurston M, Omoto M, Cherill R, Tofte SJ, Graeber M. The Eczema Area and Severity Index (EASI): assessment of reliability in atopic dermatitis. *Exp Dermatol*. 2001;10(1):11–18.
8. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)- a simple practical measure for routine clinical use. *Clin Exp Dermatol*. 1994;19(3):210–216.
9. U.S. Food and Drug Administration. Guidance for Industry: Atopic Dermatitis: Developing Drugs for Treatment. 2016.
10. U.S. Food and Drug Administration. Medical Dictionary for Regulatory Activities (MedDRA) and Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. 2017.

Disclaimer

This Clinical Study Report (CSR) has been developed for educational and demonstration purposes only.

Dermalexiin (DLX-412), MolendiiP Pharma Ltd, and the described clinical trial (DERM-001) are fictional constructs.

No actual clinical study was conducted. Accordingly, specific standard appendices typically included in a full CSR have been mentioned in the Table of Contents for completeness but have not been generated or included, specifically:

- Appendix 9.1: Patient Disposition Diagram
- Appendix 9.2: Randomisation Schedule
- Appendix 9.3: Study Protocol (DERM-001 Version 1.0)
- Appendix 9.4: Sample Case Report Form (CRF) Pages

In a real-world regulatory submission, these appendices would be fully provided to document the study design, conduct, and data collection processes.

This document is intended solely for academic, educational, and training purposes and should not be interpreted as describing or supporting any real clinical trial or investigational product.