Title:

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

Protocol Number: DERM-001

Registry Identifier: NCT0XXXXXXX (fictional)

Sponsor: MolendiiP Pharma Ltd

Phase: Phase II

Study Start Date: January 2024

Primary Completion Date: March 2025

Study Completion Date: March 2025

Locations: 4 Investigational Sites, United Kingdom

Status: Completed

Disclosure Standards Followed:

This report structure is based on the summary results reporting fields outlined by:

ClinicalTrials.gov Results Data Element Definitions (NIH, 2022)

EU Clinical Trials Regulation (EU CTR 536/2014)

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1. Participant Flow

Group	Enrolled	Completed	Discontinued	Reason(s) for Discontinuation
Dermalexiin 5% Cream	50	48	2	1 due to mild application site adverse event (AE),1 lost to follow-up
Placebo Cream	50	48	2	1 due to mild application site AE,1 lost to follow-up

2. Baseline Characteristics

Characteristic	Dermalexiin Group	Placebo Group	Overall
Participants (n)	50	50	100
Mean Age (years)	34.8 (range 18–65)	35.2 (range 18–64)	35.0
Sex (% Female)	52%	52%	52%
Baseline Mean EASI Score	18.3	18.1	18.2

3. Outcome Measures

3.1 Primary Outcome

Measure:

Percentage change from baseline in Eczema Area and Severity Index (EASI) at Week 12

Group	Mean % Change	p-value
Dermalexiin	–65%	
Placebo	–35%	p = 0.021 (ANCOVA, baseline-adjusted)

3.2 Secondary Outcomes

Change in Pruritus NRS Score at Week 12:

Group	Mean Change	p-value
Dermalexiin	–4.2 points	
Placebo	–2.1 points	p = 0.034

Change in Dermatology Life Quality Index (DLQI) Score at Week 12:

Group	Mean Change	p-value
Dermalexiin	–6.1 points	
Placebo	–3.4 points	p = 0.045

4. Adverse Events

Overview of Adverse Events

Group	Participants with ≥1 AE (%)	Most Common AEs	Serious AEs Related to Treatment
Dermalexiin	20%	Mild erythema, mild pruritus at application site	None reported
Placebo	18%	Mild erythema, mild pruritus at application site	None reported

No deaths or unexpected adverse events were reported.

All adverse events were mild and resolved without the need to discontinue the treatment, except for one participant in each group who withdrew due to local application site reactions.

Disclaimer

This Basic Results and Trial Disclosure Report was created solely for educational and demonstration purposes.

The sponsor name (MolendiiP Pharma Ltd), investigational product (Dermalexiin), and study identifier (DERM-001) are fictional.

No real clinical trial was conducted, and no absolute regulatory submission was made based on this report.

The format and structure follow general principles outlined in ClinicalTrials.gov Results Data Elements and EU Clinical Trials Regulation (EU CTR 536/2014).

However, specific registry requirements, submission processes, and real-world validation steps have been summarised or omitted for clarity.

In a regulatory setting, results must be verified according to registry-specific guidelines and applicable legal requirements.