Study Title: A phase I clinical investigation to the safety of two herbal ointment formulations for an intended treatment of Tinea corporis/cruris

Short title: ClinHerb1

Phase of the trial: Phase I

CTA Number: ET-CT-0026

Protocol No.: AHRI-IRB-PO/39/20

Version No.: 4

National Principal Investigator (NPI): Dr Adamau Bayissa

Trial Site: All Africa Leprosy, Tuberculosis, and Rehabilitation Training Center **(**ALERT) dermatology clinic

Sponsor: Ethiopian Public Health Institute (EPHI)

Ethics Approval date: 29/02/2022

Submission Date to EFDA: 28/04/2021

EFDA Status of trial (Approval or Rejection): Approved **Date:** 06/05/2025

Study Rationale

- Traditional medicine is an integral part of the local culture in Ethiopian context and used by the majority of the population regardless of the incremental expansion and accessibility of modern health services. A prevalence study conducted in Ethiopia showed that there is a high dermatophytosis. Among the clinical manifestations of the superficial fungal infections, *Tinea capitis* (28%), *Tinea corporis* (17.3%), and *Tinea unguium* (3.5%) represented in the majority of the dermatophytosis cases. The trends for emerging antimicrobial resistance demand for a continuous innovation to safe and efficacious medication. Dermatological formulations based on safe and effective medicinal herbs originated from indigenous knowledge and practice therefore could be considered in clinical developments as alternate option.

General objective / Study aims

- To evaluate the safety of the antifungal herbal formulations in human study participants which will be followed by subsequent trials to ensure the potentials of medicinal herbs formulation for the management of dermatophytosis.

Primary objectives

Objective

- To assess the safety of herbal ointment formulations, investigation medicinal product (IMP1 and IMP2), to their therapeutically proposed dose strength on healthy human skin.

Outcome measures

- Occurrence of serious adverse drug reaction(s) in comparison to placebo/vehicle for single patch test and for repeated open application tests.

Secondary Objectives and Outcome Measures

Outcome measures

- Changes from baseline vital signs (blood pressure, pulse rate, body temp & respiratory rate)
- Incidence and severity of treatment emergent adverse events
- Incidence and magnitude of treatment emergent laboratory abnormalities
- Changes from baseline on skin irritation assessment scores after treatment.

Study Design

- This is a phase I placebo controlled study for documenting safety profile of the IMPs on healthy skin.

Study Population

- All adult healthy individuals

Eligibility Criteria

Inclusion Criteria:

- Healthy male and/or female subjects of age 18+ years. Healthy is defined as no clinically relevant abnormalities identified by a detailed medical history, full physical examination & clinical laboratory tests.
- Subjects who are willing and able to comply with scheduled visits, treatment plan, laboratory tests and other study procedures.

Exclusion criteria:

- Evidence or history of clinically significant abnormalities
- Subjects with any active skin condition at the application site that can possibly affecting drug absorption.
- Subjects with a skin condition (Draize) score >0 of the test area immediately prior to first treatment application.
- Subjects using topical prescriptions or non-prescription drugs within 14 days of the first treatment application
- Subjects not willing to avoid application of treatments such as lotions or creams on the application site throughout the study follow-up.
- Pregnant and lactating woman

Study Duration

- 9 months

Investigational Medicinal Product

- Ointment formulation (coded as IMP1 and coded as IMP2)

Intervention(s)

- Formulation: Ointment formulation (coded as IMP1 and coded as IMP2)
- Dose: Once in a single patch test followed by repeated open application test twice daily over 14 days
- Route of administration: Topical

Sample size

- 30 healthy adult participants

Evaluator's Risk/Benefit Assessment:

- The study involves the use of herbal product to test its toxicity profile. Since the product is obtained from natural source, which has good safety profile with a possibility of allergic reactions, the current trial is approved, with due consideration given to the safety of the participants. and the trial will follow the principles of Good