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CLINICAL TRIAL REPORT

Clinical Trial Review is a JDD department designed to provide physicians with information on drugs and devices undergoing clinical testing. It is our goal to inform the reader of the status of select drug and device studies relevant to the practice of dermatology before this information is available through standard channels. To participate in or learn more about these and additional trials, visit www.clinicaltrials.gov.

PSORIASIS

A Multicenter Open Label Uncontrolled Study of the Long Term Safety and Efficacy of Calcitriol 3 mcg/g Ointment Applied Twice Daily for 26 Weeks in Pediatric Subjects (2 to 17 Years of Age) With Mild to Moderate Plaque Psoriasis

Sponsored by Galderma, the objective of this study is to evaluate the safety and efficacy of up to 26 weeks of treatment with calcitriol 3 mcg/g ointment when used twice daily, without occlusion, to treat pediatric subjects (2 to 17 years of age) with mild to moderate plaque psoriasis.

The inclusion criteria for this study are male or female 2 to 17 years of age with a clinical diagnosis of stable mild to moderate plaque psoriasis.

The exclusion criteria are other forms of psoriasis hypercalcemia, past history of kidney stones, Vitamin D deficiency, or other concomitant dermatological disease.

Primary outcome measures are laboratory parameters related to calcium metabolism after 26 weeks of topical treatment with Calcitriol 3 mcg/g (Time Frame: week 26) and proportion of subjects with serum albumin-adjusted calcium higher than the upper normal limit and/or Parathyroid hormone (PTH) levels below the lower limit of normal, and incidence of urolithiasis.

Condition	Intervention
Psoriasis Vulgaris	**Drug:** Calcitriol
ClinicalTrials.gov Identifier: NCT02125279	

Phase II Randomized Double Blinded Placebo Controlled, Multiple-dose Regimen Study to Assess the Rate of Histological Clearance and Effect on Molecular Pathways as Well as on Biomarkers of 12 Months Secukinumab 300 mg s.c. Treated Patients With Chronic Plaque-type Psoriasis

Sponsored by Novartis, This study is designed to evaluate the proportion of patients achieving reversal of chronic plaque psoriasis at week 4 and 12 following multiple doses of secukinumab administered subcutaneously (sc) compared to placebo. Starting from week 13, all patients will receive multiple doses of secukinumab up to week 52 to study long term effects of secukinumab. Clinical endpoints including biomarker assessments, PASI, IGA, and DLQI will be compared to better understand, why secukinumab may be effective in psoriasis patients. The primary outcome measure is for patients to achieve skin histology response after secukinumab treatment after 12 weeks of treatment.

Patients being tested have chronic plaque-type psoriasis diagnosed for at least 6 months, moderate to severe psoriasis as defined by: PASI score of ≥12, IGA score of ≥3, BSA (body surface area) affected by plaque-type psoriasis of ≥10%, and chronic plaque-type psoriasis considered inadequately controlled by: topical treatment and/or; phototherapy and/or previous systemic therapy.

Condition	Intervention
Psoriasis, Plaque-type Psoriasis	**Drug:** Secukinumab and placebo
Study ID Numbers: CAIN457A2223 **ClinicalTrials.gov Identifier:** NCT01537432	

MOLLUSCOM CONTAGIOSUM

A Dose Range-Finding Phase 2 Trial of a Botanical Drug for the Treatment of Molluscum Contagiosum in Pediatric Subjects

Sponsored by ViroXis Corporation, this trial will be a multi-center, double-blind, randomized, placebo-controlled safety and efficacy trial to evaluate the efficacy and safety of VIR003 treatment regimen when administered to pediatric subjects with molluscum contagiosum. Once subject eligibility is confirmed the subject will start the Treatment Period of the study. All subjects will receive one of three active treatments or placebo with the first dose applied at the day 0 study visit. Subjects will be instructed on how to apply the study medication twice a day for 60 days of treatment. Subjects will return to the clinic on study days, 7, 14, 30, 45, and 60 for routine evaluations and then on study day 90 for the final study visit.

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The study will be monitored by a data safety monitoring board (DSMB) comprised of a medical monitor, dermatologist and statistician. The purpose of the DSMB will be to monitor the emergence of adverse events (AEs) and serious adverse events (SAEs) at periodic intervals throughout the enrollment and treatment phases of the study.

Condition	Intervention
Molluscum Contagiosum	**Drug:** 2.5% East Indian sandalwood oil cream **Drug:** 5% East Indian sandalwood oil cream **Drug:** 10% East Indian sandalwood oil cream **Drug:** Placebo Cream
Study ID Numbers: VIR003-01 **ClinicalTrials.gov Identifier:** NCT02024581	

ACITINIC KERATOSES

An Investigator-Initiated Study to Assess the Safety and Efficacy of Ingenol Mebutate 0.05% Gel When Used After Cryotherapy in the Treatment of Hypertrophic Actinic Keratoses (AK) on Dorsal Hands

Sequential therapy with cryosurgery and ingenol mebutate may optimize the treatment of hypertrophic AKs and also treat non-hypertrophic AKs in this anatomic location. Furthermore, use of ingenol mebutate will also be evaluated for potential treatment of subclinical lesions.

The investigators plan to treat 30 subjects. Each qualifying subject will have at least 3 hypertrophic AKs, defined as more than 3mm in thickness, on each dorsal hand. Cryotherapy will be standardized in all patients and for all treated lesions: 1-2 sprays, 5 seconds each, with a 5 second interval. All subjects will be treated with the same cryo-spray. Following cryotherapy, subjects will be randomized to treat either their right or left dorsal hand with ingenol mebutate gel. The decision to treat the right vs. the left hand will be chosen by chance, like flipping a coin. Neither the subject nor the study doctor will choose what arm receives the ingenol mebutate gel. The study doctor will not know which arm is treated with ingenol mebutate, so the subject should not reveal that information to him or her at any time during the study. Subjects will treat the randomized dorsal hand with ingenol mebutate 0.05% gel starting on the same day as the cryotherapy (Day 0). Subjects will utilize the once daily for two days regimen. Subjects will be followed on day 4 after their initial visit, day 8, day 15, day 29, and day 57, with a two-day window period.

Sponsor: Mount Sinai School of Medicine	
Collaborator	**Intervention**
LEO Pharma	**Drug:** Ingenol Mebutate **Procedure:** Cryotherapy
ClinicalTrials.gov Identifier: NCT02251652	

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