A Safety, Efficacy and Pharmacokinetics Study of CD11301 for the Treatment of Cutaneous T-Cell Lymphoma (CTCL) (CTCL)

ClinicalTrials.gov Identifier: NCT03292406

Recruitment Status: Recruiting
First Posted: September 25, 2017
Last Update Posted: October 16, 2018

See Contacts and Locations

Sponsor:
Galderma R&D

Information provided by (Responsible Party):
Galderma R&D

Study Description

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Brief Summary:

To assess the efficacy, safety and pharmacokinetics in subjects treated with CD11301 gel vs. placebo for early stage CTCL (IA, IB, or IIA).

Condition or disease	Intervention/treatment	Phase
Cutaneous T Cell Lymphoma	Drug: Placebo Drug: CD11301 0.03% Drug: CD11301 0.06%	Phase 2

Detailed Description:

To assess the efficacy and safety of two concentrations (0.03% and 0.06%) of CD11301 gel in the treatment of early stage CTCL (stage IA, IB, or IIA) versus placebo.

Study Design

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Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 84 participants

Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	A Randomized, Double-blind, Multi-centre, Placebo-controlled, Parallel-arm Phase 2 Trial to Assess Safety, Efficacy and Pharmacokinetics of CD11301 0.03% and 0.06% Gel in the Treatment of Cutaneous T-Cell Lymphoma (CTCL), Stages IA, IB and IIA
Actual Study Start Date:	December 19, 2017
Estimated Primary Completion Date:	August 2019
Estimated Study Completion Date:	August 2019

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Lymphoma

Genetic and Rare Diseases Information Center resources: Lymphosarcoma Cutaneous T-cell Lymphoma

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Group 1 Placebo followed by CD11301 (0.03%) Topical Gel	Drug: Placebo Non active ingredients of CD11301 Drug: CD11301 0.03% Topical Gel
Experimental: Group 2 CD11301 (0.03%) Topical Gel	Drug: CD11301 0.03% Topical Gel
Experimental: Group 3 CD11301 (0.06%) Topical Gel	Drug: CD11301 0.06% Topical Gel

Outcome Measures

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Primary Outcome Measures:

1. Overall response rate of target lesions at Week 12 based on CAILS score. [Time Frame: Week 12]

   Overall response rate (Complete and Partial Response) of target lesions based on the Composite Assessment of Index Lesion Severity (CAILS) score.

Secondary Outcome Measures:

1. Overall response rate based upon mSWAT composite score at Week 12. [Time Frame: Week 12]

   Overall response rate (Complete and Partial Response) based upon mSWAT composite score.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Clinical Diagnosis of CTCL stage IA, IB, or IIA with biopsy within last 3 months
- Have BSA involvement corresponding to stages IA, IB or IIA CTCL with at least 3 distinct lesions

Exclusion Criteria:

- CTCL that is stage IIB or great or stage IIA with stage N2 with >5% circulating Sezary cells or CD8+ or large cell transformation or Progressive CTCL
- History of autoimmune disease
- Laboratory test values at screening outside of the normal range and judged clinically significant by the investigator
- Current participation in another clinical trial of a drug or device or past participation within 4 weeks before Baseline or subject is in exclusion period from a previous clinical trial

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03292406***

Contacts

Contact: Galderma R&D 817-961-5120 frnceclinicaltrials@galderma.com

Locations

United States, California

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Orange, California, United States, 92868
Contact: Galderma Investigational Site

Galderma Investigational Site **Recruiting**
Palo Alto, California, United States, 94304
Contact: Galderma Investigational Site

United States, Connecticut

Galderma Investigational Site **Recruiting**
Farmington, Connecticut, United States, 06032
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United States, Illinois

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Chicago, Illinois, United States, 60611
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United States, Massachusetts

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United States, North Carolina

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United States, Pennsylvania

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Dallas, Texas, United States, 75231
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Contact: Galderma Investigational Site

Galderma Investigational Site **Withdrawn**
Pflugerville, Texas, United States, 78660

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Sponsors and Collaborators

Galderma R&D

Investigators

Study Director: Galderma R&D Galderma R&D

More Information

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Responsible Party:	Galderma R&D
ClinicalTrials.gov Identifier:	NCT03292406 History of Changes
Other Study ID Numbers:	RD.03.SPR.104003
First Posted:	September 25, 2017 Key Record Dates
Last Update Posted:	October 16, 2018
Last Verified:	July 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	No intent to share information.

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Galderma R&D:

T-Cell

Lymphoma

Cutaneous

CTCL

Additional relevant MeSH terms:

Lymphoma

Lymphoma, T-Cell

Lymphoma, T-Cell, Cutaneous

Neoplasms by Histologic Type

Neoplasms

Lymphoproliferative Disorders

Lymphatic Diseases

Immunoproliferative Disorders

Immune System Diseases

Lymphoma, Non-Hodgkin