A Phase 3, Double-Blind, Randomized, Vehicle-Controlled, Efficacy and Safety Study of Ruxolitinib Cream Followed by an Extension Period in Participants With Vitiligo

Published: 19-02-2020
Last updated: 08-04-2024

Primary:To evaluate the efficacy of ruxolitinib cream in participants with vitiligo.Secondary:To further assess the efficacy of ruxolitinib cream.To evaluate the safety and tolerability of ruxolitinib cream.To evaluate the ruxolitinib PK in plasma...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49311

Source
ToetsingOnline

Brief title
TRuE-V2

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
leucoderma, white patches of skin

Research involving
Human

Sponsors and support

Primary sponsor: Incyte Corporation
Source(s) of monetary or material Support: Incyte Corporation

Intervention

Keyword: Phase 3, Ruxolitinib, Vehicle-Controlled, Vitiligo

Outcome measures

Primary outcome

Proportion of participants achieving F-VASI75 at Week 24.

Secondary outcome

• Percentage change from baseline in F-BSA at Week 24.

• Proportion of participants achieving F-VASI50 at Week 24.

• Proportion of participants achieving F-VASI75 at Week 52.

• Proportion of participants achieving F-VASI90 at Week 24.

• Proportion of participants achieving F-VASI90 at Week 52.

• Proportion of participants achieving T-VASI50 at Week 24.

• Proportion of participants achieving T-VASI50 at Week 52.

• Proportion of participants achieving T-VASI75 at Week 52.

• Proportion of participants achieving a VNS of *4 - A lot less noticeable* or *5 - No longer noticeable* at Week 24.

• The frequency, duration, and severity of AEs; physical examinations; vital signs; and laboratory data for hematology and serum chemistry.

• Proportion of participants achieving F-VASI25/50/75/90 during the treatment period (double-blind and treatment extension periods).

• Proportion of participants achieving T-VASI25/50/75/90 during the treatment

period (double-blind and treatment extension periods).

• Proportion of participants in each category of VNS during the treatment

period (double-blind and treatment extension periods).

Study description

Background summary

Ruxolitinib cream is a topical formulation of ruxolitinib phosphate under development for the treatment of participants with AD, AA,plaque psoriasis, and vitiligo. Ruxolitinib phosphate is an inhibitor of the JAK family of protein TYKs. Inflammatory cytokines are strongly implicated in the pathogenesis of several dermatologic diseases. Because JAKs serve to translate extracellular signals from a number of relevant cytokines and growth factors upregulated in inflammatory diseases such as AD, AA, plaque psoriasis,and vitiligo, JAK inhibitors represent potential therapeutic agents for these disease states.

This is a randomized, vehicle-controlled study in adolescent and adult participants (age >= 12 years) with non-segmental vitiligo who have depigmented area including >= 0.5% BSA on the face, >= 0.5 F-VASI, >= 3% BSA on nonfacial areas, and >= 3 T-VASI. Total body involved vitiligo area (facial and nonfacial) should not exceed 10% BSA. Approximately 300 participants will be randomized 2:1 to receive initial study treatment (ruxolitinib cream 1.5% BID:vehicle; applied to depigmented vitiligo areas on the face and body up to 10% total BSA) for 24 weeks

After completion of the Week 24 assessments, participants will be offered the opportunity to receive an additional 28 weeks of treatment extension with ruxolitinib cream 1.5% BID. To be eligible for the treatment extension, participants must have completed the baseline and Week 24 visit assessments, be compliant with study procedures, and not have any safety issues. The total treated area should not exceed 10% BSA (facial and nonfacial).

Participants who successfully complete the 52-week treatment in this study may be eligible to participate in a separate extension study to evaluate durability of effect and maintenance regimens.

Study objective

Primary:
To evaluate the efficacy of ruxolitinib cream in participants with vitiligo.

Secondary:
To further assess the efficacy of ruxolitinib cream.
To evaluate the safety and tolerability of ruxolitinib cream.
To evaluate the ruxolitinib PK in plasma after treatment of ruxolitinib cream.

Study design

Randomized, double-blind, vehicle-controlled, with a treatment extension period.

Intervention

ruxolitinib cream 1.5% /:vehicle

Study burden and risks

Burden and risks:
- Possible side effects from the treatment (side effects are described in Appendix D of the ICF)
- Discomfort, soreness, bruising: in rare cases infection, light headedness/fainting from blood drawing
- Rash or irritation from ECG sticky pads.
- Commitment to follow instructions associated with the study treatment and visits schedule

Currently, there are no approved therapies for vitiligo, and treatments are empirical and directed by the available clinical guidelines. Current therapies often do not lead to satisfactory response, and there are limitations and safety concerns with long-term use of some therapies, including topical or oral corticosteroids and calcineurin inhibitors. Given the psychosocial burden and stigma that has been reported in this disease, patients with vitiligo warrant access to new studies.

Contacts

Public
Incyte Corporation

Augustine Cut-Off 1801
Wilmington 19803
US
Scientific
Incyte Corporation

Augustine Cut-Off 1801
Wilmington 19803
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adolescents and adults aged >= 12 years.
- Participants with a clinical diagnosis of non-segmental vitiligo with depigmented area including >= 0.5% BSA on the face, >= 0.5 F-VASI, >= 3% BSA on nonfacial areas, >= 3 T-VASI, and total body vitiligo area (facial and non-facial) not exceeding 10% BSA.
- Participants who agree to discontinue all agents used to treat vitiligo from screening through the final safety follow-up visit. Over-the-counter preparations deemed acceptable by the investigator and camouflage makeups are permitted.

Exclusion criteria

- Participants who have no pigmented hair within any of the vitiligo areas on the face.
- Other forms of vitiligo (eg, segmental) or other differential diagnosis of vitiligo or other skin depigmentation disorders (eg, piebaldism, pityriasis alba, leprosy, postinflammatory hypopigmentation, progressive macule hypomelanosis, nevus anemicus, chemical leukoderma, and tinea versicolor).
- Participants who have used depigmentation treatments (eg, monobenzone) for past treatment of vitiligo or other pigmented areas.
Note: Prior use of hydroquinone is not prohibited (as it is a bleaching agent,

not a depigmentation treatment).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-07-2020
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ruxolitinib cream
Generic name:	INCB018424 PHOSPHATE CREAM 1.5%

Ethics review

Approved WMO Date:	19-02-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-000847-28-NL
ClinicalTrials.gov	NCT04057573
CCMO	NL70922.018.20