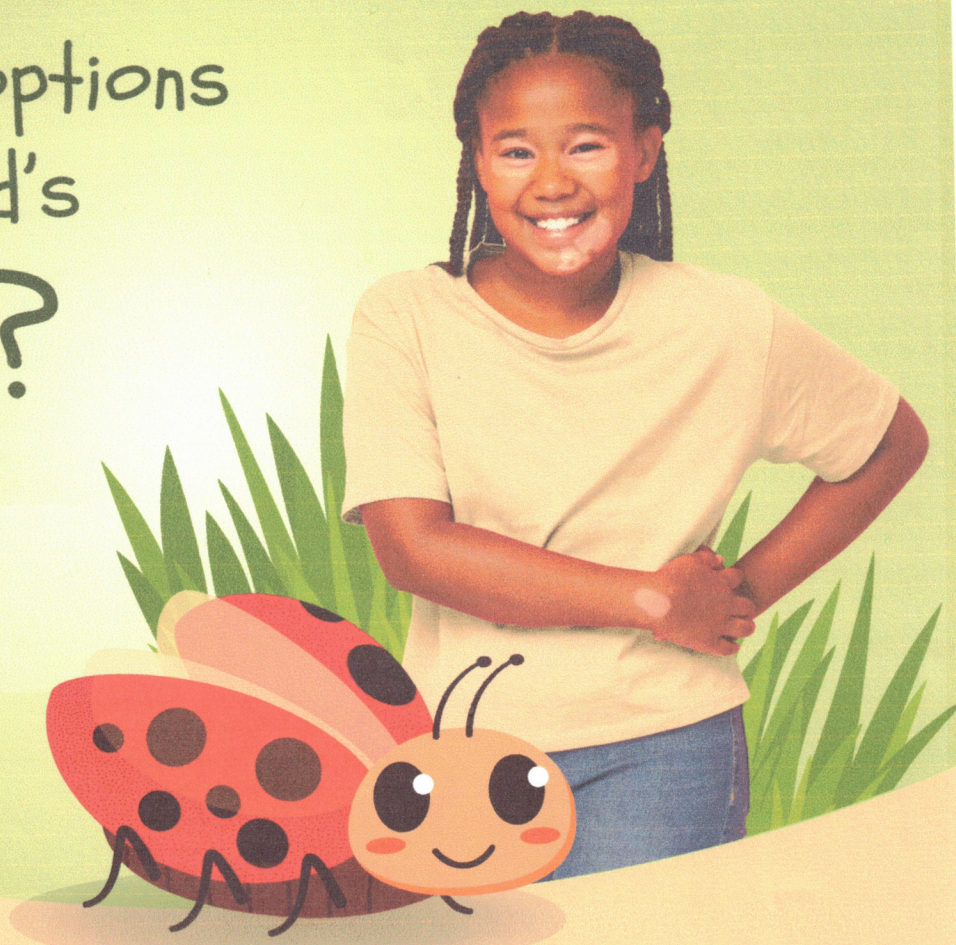


Looking for options for your child's vitiligo?

Find out about the
TRuE-ViP Study



The TRuE-ViP Study will study how well an investigational cream may work to treat children with vitiligo on the face and body.

To join the study, your child must:

- Be 2 to 11 years old
- Have nonsegmental vitiligo
- Have vitiligo on the face and at least one other body region

There are other requirements for taking part in this study. The study team will go over details with you and see if your child may qualify.

Children who qualify for the study will:

- Attend 11 visits over 14 months
- Receive treatment with the study cream and all study related care at no cost

Be reimbursed for reasonable time and travel costs during participation.

Contact us to find out more about the
TRuE-ViP Study:

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TRuE-ViP

INCB 18424-312_Flyer_v1.0_US Eng_27SEP2024

The TRuE-ViP Study

Fact Sheet for Healthcare Providers



Protocol Title: A Phase 3, Randomized, Double-Blind, Safety and Efficacy Study of Ruxolitinib Cream in Pediatric Participants With Nonsegmental Vitiligo

Protocol Number: INCB 18424-312

Clinicaltrials.gov Number: NCT06548360

Phase of Development: Phase 3

Study Treatment

Vitiligo is an autoimmune pigmentary disease that affects up to 2% of people worldwide and is characterized by progressive loss of functional melanocytes, which appears as well-circumscribed white macules and patches on the skin.

Ruxolitinib cream (Opzelura®) has been approved in the United States, European Union, and United Kingdom to treat nonsegmental vitiligo in adults and adolescents 12 years of age or older. With no approved repigmenting therapies for children younger than 12, management of their vitiligo is limited to empirical treatments like topical corticosteroids, topical calcineurin inhibitors, and narrowband UVB phototherapy.

Study Objectives

Primary Objective:

- To evaluate the efficacy of ruxolitinib cream in pediatric participants with nonsegmental vitiligo

Key Secondary Objective:

- To further assess the efficacy of ruxolitinib cream at week 24

Other Secondary Objectives:

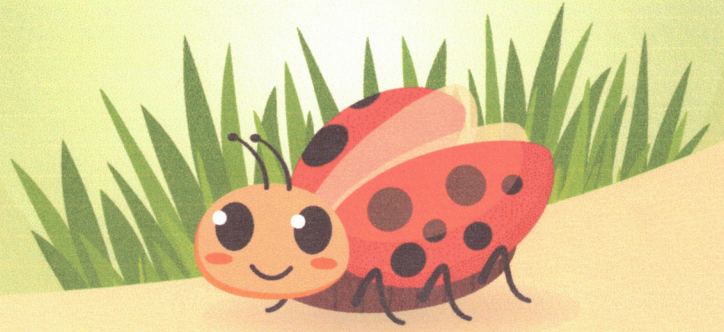
- To evaluate the safety and tolerability of ruxolitinib cream
- To further assess the efficacy of ruxolitinib cream at weeks 24 and 52
- To evaluate the ruxolitinib PK after treatment of ruxolitinib cream

Length of Study

The TRuE-ViP Study lasts up to 14 months across 11 study visits and includes:

- **Screening period:** Up to 30 days
- **Treatment period:** 52 weeks
- **Follow-up:** 30 days after the last application of the study cream

TRuE-ViP[®]



Study Overview

The TRuE-ViP Study will test safety and efficacy of ruxolitinib cream in pediatric participants with nonsegmental vitiligo. During the first 24 weeks of the treatment period, participants in the TRuE-ViP Study will be randomized 1:1 to receive either:

- Ruxolitinib 1.5% cream
- Vehicle cream

The participant or their parent/guardian will apply study or vehicle cream twice daily to affected areas on the face and body for 24 weeks. Participants who complete 24 weeks of treatment with no safety concerns will continue into a 28-week, open-label extension and be treated with ruxolitinib 1.5% cream twice daily. After the last dose, participants will be followed for 30 days.

Key Eligibility Criteria

To join the TRuE-ViP Study, participants must

- Be aged 2 to <12 years at the screening visit
- Have a clinical diagnosis of nonsegmental vitiligo with depigmented area, including:
 - $\geq 0.5\%$ body surface area on the face
 - ≥ 0.5 Face Vitiligo Area Scoring Index
 - $\geq 3\%$ body surface area on nonfacial areas
 - ≥ 3 Total Body Vitiligo Area Scoring Index
- Not have total body vitiligo area (facial and nonfacial) $> 10\%$ of the body surface area

Other inclusions/exclusions apply.

Potential Risks to Participants

Not all of the risks or side effects of the study cream are yet known. As with all medicines, ruxolitinib can cause side effects in some participants. Most side effects are mild to moderate and may include, but are not limited to:



Infections



Itching



Acne



Headache



Common cold

Potential Benefits to Participants

Participants may not receive a direct benefit from taking part in the TRuE-ViP Study. Participation is likely to lead to a better understanding of the effectiveness and safety of ruxolitinib as a potential treatment for children and adolescents with nonsegmental vitiligo.

For more information about the TRuE-ViP Study, please contact:

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