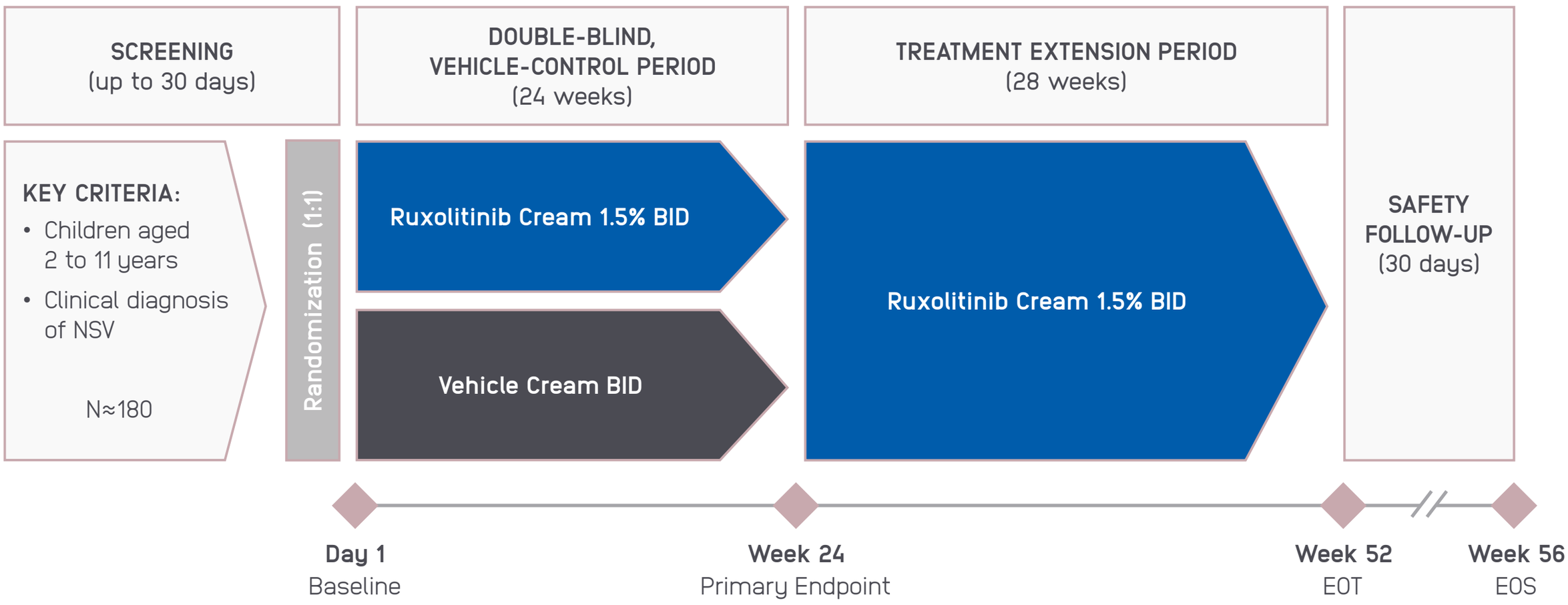
PEDIATRIC NONSEGMENTAL VITILIGO

NCT06548360

Incyte Dermatology

SOLVE ON.

Phase 3, Randomized, Double-Blind, Vehicle-Controlled Study of the Efficacy and Safety of Ruxolitinib Cream in Children With Nonsegmental Vitiligo



1 PRIMARY ENDPOINT:

- Proportion of patients achieving F-VASI75 at week 24

2 SELECT SECONDARY ENDPOINTS:

- Proportion of patients achieving F-VASI50 at weeks 24 and 52
- Proportion of patients achieving F-VASI90 at weeks 24 and 52
- Proportion of patients achieving T-VASI50 at weeks 24 and 52
- Percentage change from baseline in F-BSA at week 24
- Number of TEAEs up to week 52 and 30-day follow-up

For more information, please visit: https://clinicaltrials.gov/study/NCT06548360

SELECT INCLUSION CRITERIA

- Children 2 to 11 years of age
- Clinical diagnosis of NSV with depigmented area affecting ≥0.5% BSA on the face, ≥0.5 F-VASI, ≥3% BSA on nonfacial areas, and ≥3 T-VASI
- Total body vitiligo area not to exceed 10% BSA
- Pigmented hair within some of the areas of vitiligo on the face

SELECT EXCLUSION CRITERIA

- Diagnosis of other forms of vitiligo (eg, segmental), other differential diagnosis of vitiligo, or other skin depigmentation disorders
- Any other skin disease, serious illness or medical, physical, or psychiatric condition(s) that, in the opinion of the investigator, would interfere with the full participation in the study
- Prior or current use of depigmentation treatments or systemic or topical JAK inhibitors

The efficacy and safety of the investigational compound and/or uses discussed have not been established. There is no guarantee that this compound will become commercially available for the use(s) under investigation.

For more information, visit **IncyteClinicalTrials.com** or contact us at **1-855-4MEDINFO** (855-463-3463) or by email at **clintrials@incyte.com**

BID, twice daily; BSA, body surface area; EOS, end of study; EOT, end of treatment; F-BSA, facial body surface area; F-VASI, facial vitiligo area score index; F-VASI50/75/90, ≥50%/75%/90% improvement from baseline in F-VASI; JAK, Janus kinase; NSV, nonsegmental vitiligo; T-VASI, total body vitiligo area score index; T-VASI50, ≥50% improvement from baseline in T-VASI; TEAE, treatment-emergent adverse event.

US and Canada registrational study.
ClinicalTrials.gov. NCT06548360. Accessed June 2025. https://clinicaltrials.gov/study/NCT06548360. Data on file; Incyte Corporation.

This information is current as of June 11, 2025