NOVARTIS

Information about **the VITESS clinical study** for people living with non-segmental vitiligo

Introduction

Vitiligo is a chronic, autoimmune condition that presents as depigmented macules and patches, resulting from the loss of functional melanocytes, affecting 0.5–1% of the global population.[1–3] Although vitiligo is an autoimmune condition, it is frequently mischaracterized as a cosmetic or trivial condition – yet those affected often experience significant quality-of-life challenges including depression and anxiety, social isolation, and work absence.[4–7]

Current treatment options are limited; there are currently no systemic medications that repigment affected areas, and many people do not see meaningful improvements with current treatments. Therefore, there remains a high clinical need for more effective and safer treatments. That's why we're conducting VITESS – a clinical study to determine if GIA632 can help to repigment affected areas.

Background on GIA632

GIA632 is an investigational monoclonal antibody that binds to and inhibits IL-15. IL-15 is implicated in vitiligo pathogenesis through two key mechanisms:[8–10]

- Activation and persistence of autoreactive CD8+ T cells
- Maintenance of tissue-resident memory T cells (TRMs) in lesions and perilesional skin

TRMs contribute further to disease activity by releasing pro-inflammatory cytokines such as IFN-ɣ, a key mediator in vitiligo that drives melanocyte apoptosis and depletion.[8,11,12]

In pre-clinical studies, blocking the IL-15 signaling pathway reduces or reverses disease progression and removes TRMs from the skin, suggesting durable repigmentation.[13] Given the association between IL-15 levels and disease severity, it's hoped that the investigational medicine will stabilize depigmentation and repigment affected areas.

Study population

To be eligible for this study, participants must (in addition to other criteria):

- Be aged 18 years and over
- Be diagnosed with non-segmental vitiligo
- Have had inadequate response to at least one topical treatment for at least 3 months, or such treatments being considered not advisable

Patients are excluded from entering the study if they:

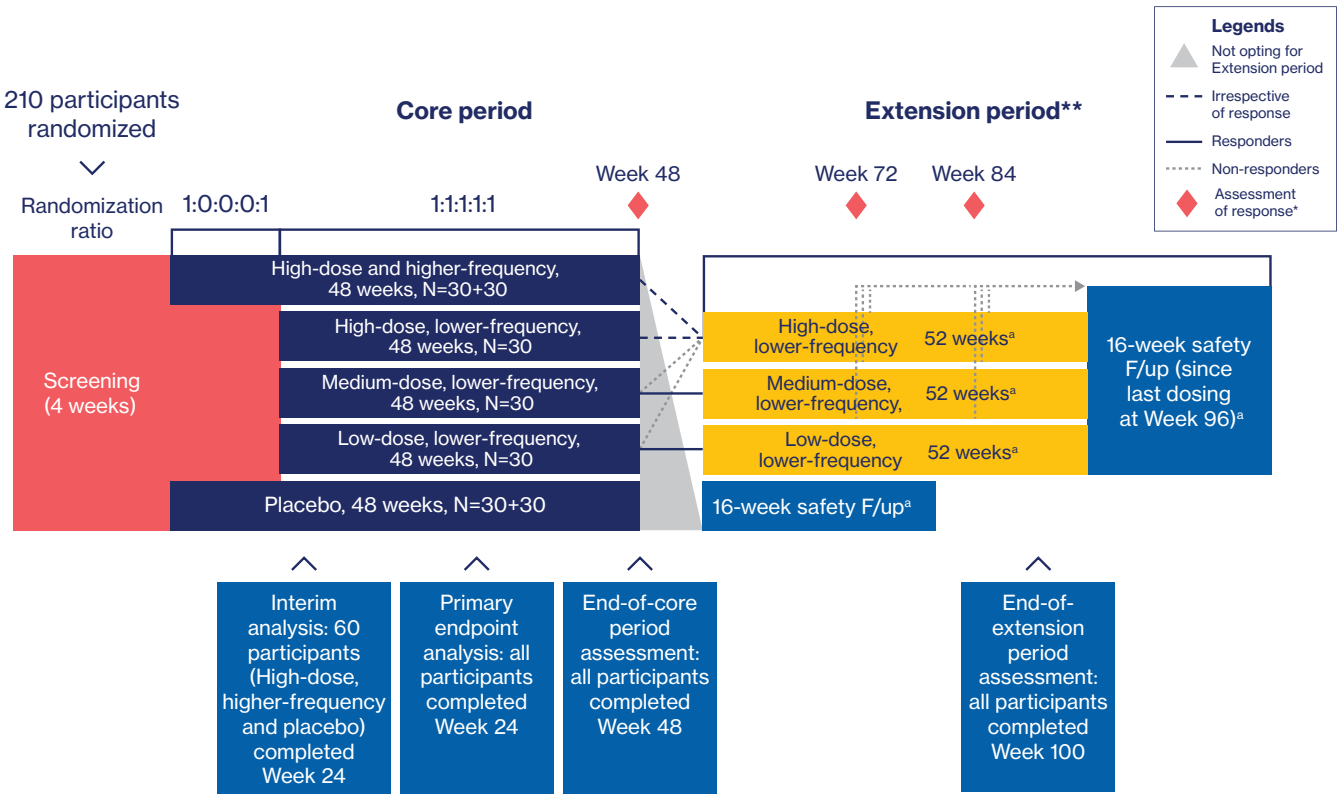
- Have not responded to systemic JAK inhibitors or TYK2 inhibitors
- Have previously attempted or completed depigmentation therapy
- Have segmental or mixed vitiligo, or other skin comorbidities that may interfere with study assessments (e.g., hypopigmented mycosis fungoides, genetic diseases with pigmentary aberrations, chemical- or drug-induced leukoderma, etc.)

Study design

VITESS is a multicenter, randomized, double-blind, placebo-controlled Phase 2b study to investigate the safety and efficacy of GIA632 in participants with non-segmental vitiligo and to identify the optimal dose to be promoted into the confirmatory Phase 3 program. People who join VITESS will take part for up to 1 year and 4 months (including screening and follow-up periods). Participants will be randomized to receive GIA632 at different doses and frequencies, or placebo. The first 60 participants will be randomized to either the high-dose, higher-frequency GIA632 group, or the placebo group with the same frequency.

The remaining participants will then be randomized into one of five groups: high-dose and higher-frequency, high-dose and lower-frequency, medium-dose and lower-frequency, low-dose and lower-frequency, or placebo.

To maintain blinding across all groups, participants assigned to the lower-frequency regimen will be given placebo injections to mimic the higher-frequency regimen. Participants who complete the double-blind period (and meet additional criteria) will be given the option to join the extension period for an additional 1 year.



[a] Investigators may allow participants to receive either narrowband UVB (nbUVB) therapy or excimer laser/lamp treatment, targeting all body lesions, during the 52-week extension period and during the 16-week safety follow-ups (both core and extension safety follow-ups). NbUVB and/or excimer laser/lamp treatment is/are not allowed in the core treatment period.

* Non-responder is defined as a participant who fails to achieve F-VASI50 (i.e., <50% change in Facial-Vitiligo Area Scoring Index [F-VASI] compared to Day 1). Based on assessment at Week 48, participants willing to participate in the 52-week extension period, will be allocated in the following arms:

1) All participants from the placebo, high-dose, higher-frequency and high-dose, lower-frequency arms, irrespective of the response at Week 48 of the core period, will receive high-dose, lower-frequency GIA632
2) Responders (i.e., participants who achieve F-VASI50 compared to Day 1) from the medium-dose, lower-frequency and low-dose, lower frequency arms will continue their respective regimens
3) Non-responders (i.e., participants who fail to achieve F-VASI50 compared to Day 1) from the medium-dose, lower-frequency and low-dose, lower-frequency arms will receive high dose, higher-frequency GIA632

Participants unwilling to participate in the extension period will be observed under the 16-week safety follow-up. Assessment of response during the extension period is scheduled at Week 72 and Week 84 where non-responders will be discontinued from treatment, at that respective visit, regardless of treatment arm.

** All study treatments in the extension period are administered in a blinded manner.

Objectives and endpoints

The primary objective of the VITESS study is to determine the dose-response relationship of GIA632 and evaluate the efficacy of the targeted doses compared to placebo in promoting facial skin re-pigmentation at Week 24 with respect to the percentage change from baseline in F-VASI score, in participants with NSV.

The primary endpoint is percentage change from baseline to Week 24 in F-VASI score.

Endpoints for secondary objectives include:

- Achievement of ≥75% improvement from baseline in F-VASI score (F-VASI75) at Week 24
- Achievement of ≥50% improvement from baseline in F-VASI score (T-VASI50) at Week 24
- Achievement of F-VASI50, F-VASI75 and F-VASI90 at Weeks 12, 24, 36, and 48
- Achievement of Vitiligo Noticeability Scale (VNS) score of 4 or 5 at Weeks 12, 25, 36, and 48
- Occurrence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)

Refer a patient

If you have any patients who may be eligible for this study, or if you would like more information, please contact the VITESS study team.

Study team contact details:

References

1. Duplaine A, et al. Ann Dermatol Venereol. 2025;152:103352; **2.** Passeron T, Ortonne JP. Vitiligo and Other Disorders of Hypopigmentation. In Bolognia JL, Schaffer, JV, Cerroni L (ed.) Dermatology. 5th ed. Amsterdam: Elsevier Ltd;2024;1098–1124; **3.** Ezzedine K, et al. Pigment Cell Melanoma Res. 2012;25:E1–E13; **4.** Radtke MA, et al. Dermatology. 2010;220:194–200; **5.** Teasdale E, et al. BMJ Open. 2018;8:e018652; **6.** Ezzedine K, et al. Am J Clin Dermatol. 2021;22:757–774; **7.** Bibeau K, et al. J Eur Acad Dermatol Venereol. 2022;36:1831–1844; **8.** Strassner JP, Harris JE. Curr Opin Immunol. 2016;43:81–88; **9.** Riding RL, Harris JE. J Immunol. 2019;203:11–19; **10.** Tieu R, et al. Sci Immunol. 2023;8:eadd8454; **11.** Rodriques M, et al. J Am Acad Dermatology. 2017;77;1–13; **12.** Paganelli A, et al. Life (Basel). 2025;15:684; **13.** Richmond JM, et al. Sci Transl Med. 2018;10:p.eaam7710.