IGNYTE-3 study sites

If you have a potential patient who may qualify for the clinical trial, please scan the QR code below or contact Replimune's clinical trial team for more information on sites recruiting for this study.

You can email **clinicaltrials@replimune.com**

Scan the QR code to view trial sites as well as additional details at replimune.com/clinical-trials/ignyte-3

References:

1. IGNYTE 3 Clinical Trial Protocol, Original (Data on file).
2. IGNYTE Clinical Trial Protocol Amendment 12, September 2, 2022 (Data on file).
3. RP1 and Nivolumab vs Physician's Choice in Advanced Melanoma That Progressed on Anti-PD-1 & Anti-CTLA-4 Drugs (IGNYTE-3). ClinicalTrials.gov NCT06264180. Updated February 16, 2024. Accessed April 26, 2024. https://www.clinicaltrials.gov/study/NCT06264180?term=NCT06264180&rank=1#participation-criteria

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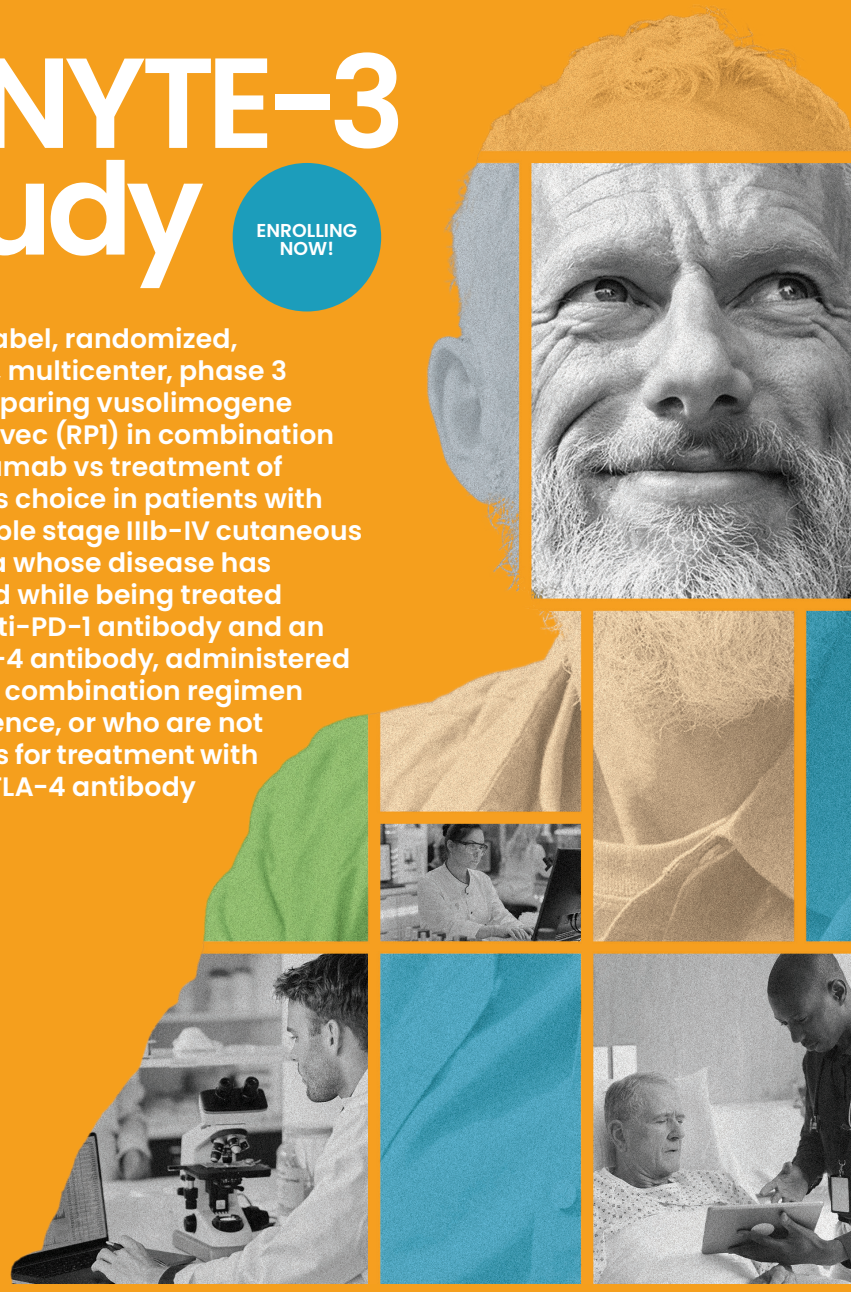
Important: Vusolimogene oderparepvec (RP1) is an investigational therapy and its use in combination with nivolumab has not been proven to be safe or effective, and has not been approved by the United States Food and Drug Administration (FDA) or any other regulatory agency outside of the US.

RP1

IGNYTE-3 Study

ENROLLING NOW!

An open-label, randomized, controlled, multicenter, phase 3 study comparing vusolimogene oderparepvec (RP1) in combination with nivolumab vs treatment of physician's choice in patients with unresectable stage IIIb-IV cutaneous melanoma whose disease has progressed while being treated with an anti-PD-1 antibody and an anti-CTLA-4 antibody, administered either as a combination regimen or in sequence, or who are not candidates for treatment with an anti-CTLA-4 antibody



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IGNYTE-3 Study Overview

IGNYTE-3 is a follow-up trial to the IGNYTE study. It aims to assess efficacy and safety of RP1 with nivolumab in a larger cohort of advanced melanoma patients whose disease has progressed on anti-PD-1 and anti-CTLA-4 therapy or are ineligible for anti-CTLA-4 treatment. The potential for an anti-tumor immune response via lytic virus replication as well as via production of tumor neoantigens has the opportunity to synergize with immune checkpoint blockade agents such as those targeting the PD-1 receptor.[1,2]

ClinicalTrials.gov ID[3]	**NCT06264180**
Tumor type[1]	**Unresectable or metastatic stage IIIB/IV cutaneous melanoma**

Intervention[1]	• **RP1 + nivolumab** or
	• **Treatment of physician's choice (one of the following)**
	  • Combination therapy (nivolumab + relatlimab)
	  • Anti-PD-1 monotherapy (nivolumab or pembrolizumab)
	  • Single-agent chemotherapy (dacarbazine, temozolomide, or paclitaxel/albumin-bound paclitaxel)

Estimated enrollment[3]	**400**

Key inclusion criteria[1,3]

- Aged ≥12 years, male or female
- Unresectable or metastatic stage IIIb through IV/M1a through M1d cutaneous melanoma
- Confirmed disease progression (PD) on an approved anti-PD-1 and an anti-CTLA-4 treatment, administered either as a combination regimen or in sequence
- Maximum 2 lines of systemic therapy for advanced disease
- BRAF mutant patient must have been treated with BRAF/MEK-directed therapy
- At least 1 measurable and injectable lesion tumor of ≥1 cm in longest diameter (or shortest diameter for lymph nodes)
- No prior oncolytic immunotherapy

Study endpoints[1,2]

Key primary endpoints

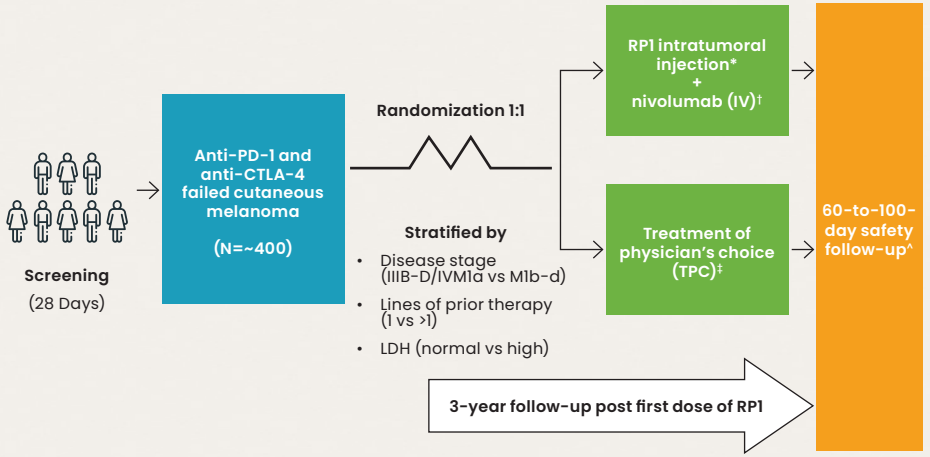
- Overall survival (OS)

Select secondary endpoints

- Progression-free survival (PFS)
- Objective response rate (ORR)

IGNYTE-3 study design[1]

Patients will be screened for up to 4 weeks, followed by a 2-year treatment period, and a 60-to-100-day safety follow-up period after the last dose of treatment.



*RP1 administered intratumorally every 2 weeks (8 injections per course).
†Nivolumab administered intravenously at 240 mg Q2W or 480 mg Q4W.
‡TPC, choosing from 1 of the following: Nivolumab + relatlimab or anti-PD-1 monotherapy (nivolumab or pembrolizumab) or single-agent chemotherapy (dacarbazine, temozolomide, or paclitaxel/albumin-bound paclitaxel).
^Patients in the RP1 + nivolumab group will complete safety follow-up visits at the following time points: 60 days after the last dose of RP1 and 100 days after the last dose of nivolumab. Patients in the TPC group will complete safety follow-up visits at 60 days after the last dose of single-agent chemotherapy and 100 days after the last dose of nivolumab, nivolumab + relatlimab, or pembrolizumab.

BRAF: v-raf murine sarcoma viral oncogene homolog B1; CTLA-4: cytotoxic T-lymphocyte antigen-4; LDH: lactate dehydrogenase; PD-1: programmed cell death protein 1; Q2W: once every 2 weeks; Q4W: once every 4 weeks; RP1: vusolimogene oderparepvec.

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