REVEAL study sites

State	City	Institute
Arizona	Scottsdale	Honor Health Research Institute
California	La Jolla	UC San Diego Moores Cancer Center
	Los Angeles	The Angeles Clinic and Research Institute
	Palo Alto	Stanford Cancer Center
District of Columbia	Washington	Georgetown University Medical Center
Georgia	Atlanta	Emory Winship Cancer Institute
Illinois	Chicago	Northwestern Memorial Hospital
Iowa	Iowa City	University of Iowa
North Carolina	Durham	Duke Cancer Center
Pennsylvania	Philadelphia	Thomas Jefferson University
	Pittsburgh	UPMC Hillman Cancer Center
Tennessee	Nashville	Sarah Cannon Research Institute
Texas	Houston	The University of Texas MD Anderson Cancer Center
Wisconsin	Madison	University of Wisconsin Carbone Cancer Center

Since the list of clinical trial sites is often updated, it is essential to refer to the latest information available. If you have a potential patient who may qualify for the clinical trial, please contact Replimune's clinical trial team for more information on sites recruiting for this study.

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

Scan to view additional details on Replimune's corporate website at replimune.com/clinical-trials/rp2-202/

References:

1. Khoja L, Atenafu EG, Suciu S, Leyvraz S, Sato T, Marshall E, et al. Meta-analysis in metastatic uveal melanoma to determine progression free and overall survival benchmarks: an international rare cancers initiative (IRCI) ocular melanoma study. *Ann Oncol.* 2019;30(8):1370-1380.
2. RP2-202 Clinical Study Protocol Version 1.0 – May 17, 2025 (Data on file)
3. A randomized, phase 2/3 study to investigate the efficacy and safety of RP2 in combination with nivolumab in immune checkpoint inhibitor-naïve adult patients with metastatic uveal melanoma (RP2-202). ClinicalTrials.gov NCT06581406. Updated November 20, 2024. Accessed January 13, 2025. https://clinicaltrials.gov/study/NCT06581406

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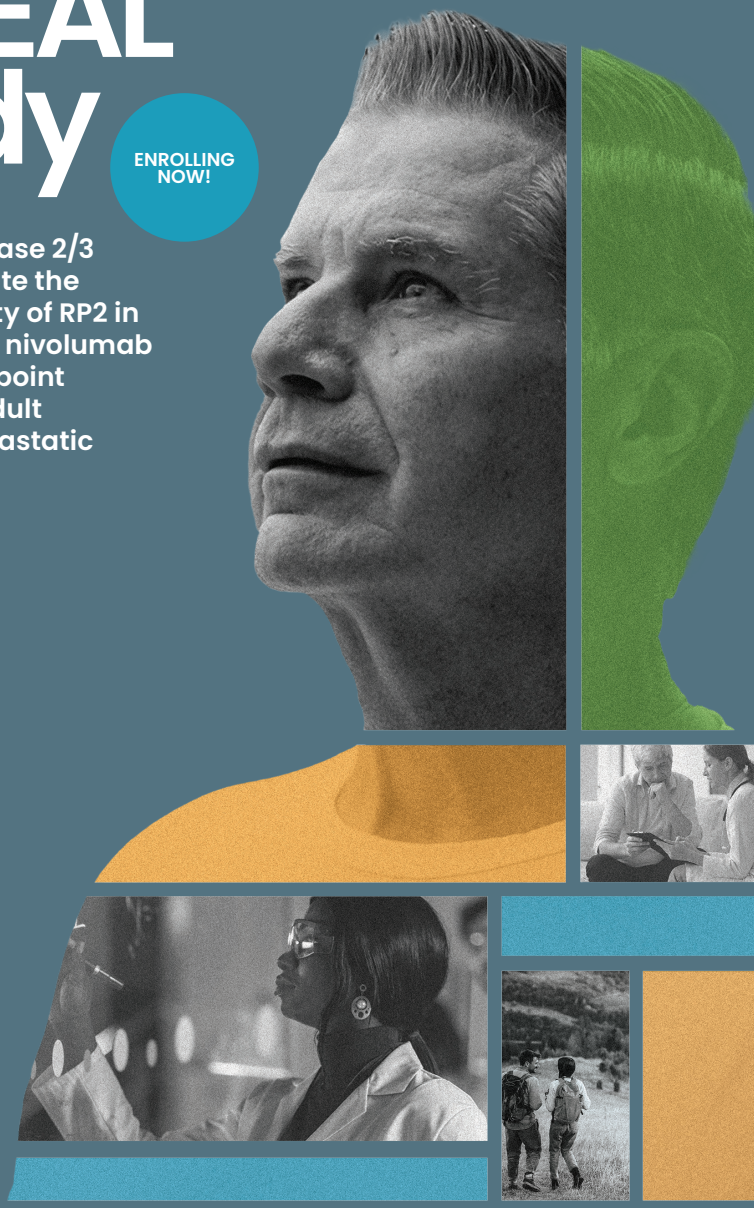
Important: RP2 is an investigational therapy and its use in combination with nivolumab has not been proven to be safe or effective, and has not been approved by the United States Food and Drug Administration (FDA) or any other regulatory agency outside of the US.

RP2

REVEAL Study

ENROLLING NOW!

A randomized, Phase 2/3 study to investigate the efficacy and safety of RP2 in combination with nivolumab in immune checkpoint inhibitor-naïve adult patients with metastatic uveal melanoma



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REVEAL Study Overview

Historically, in metastatic uveal melanoma, median progression-free survival (PFS) is generally less than 5 months and median overall survival (OS) less than 12 months.[1] These results imply substantial unmet needs among patients with metastatic uveal melanoma, given the poor prognoses and considerable toxicities associated with current standards of care. Irrespective of human leukocyte antigen (HLA)-A*02:01 status, there is an urgent demand for novel and effective therapies for metastatic uveal melanoma.

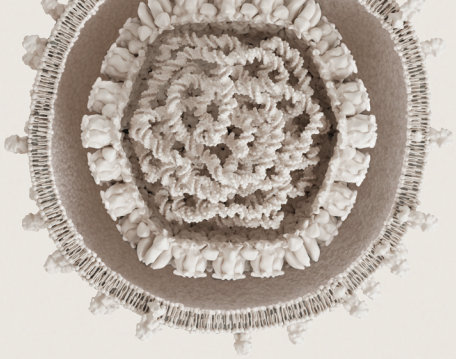
ClinicalTrials.gov ID[2,3]	**NCT06581406**
Tumor type[2,3]	**Metastatic uveal melanoma**
Intervention[2,3]	• **RP2 + nivolumab** • **Ipilimumab + nivolumab**
Estimated enrollment[2,3]	**~280**

Key inclusion criteria[2,3]

- Age ≥18 years
- Metastatic uveal melanoma not amenable to surgical resection
- At least 1 measurable and injectable tumor of ≥1 cm in longest diameter
- Must be willing to provide tumor biopsy samples
- LDH ≤2 x ULN
- Adequate hematologic, hepatic, coagulation, and renal function
- ECOG performance status 0 or 1
- Life expectancy of >3 months as estimated by the investigator

Key exclusion criteria[2,3]

- Any exposure to ICIs and more than one line of systemic therapy since the time of first being diagnosed with metastatic uveal melanoma
- Any CNS involvement of melanoma, including carcinomatous meningitis
- Any bleeding, thrombotic, and/or other event that places the patient at an unacceptable risk of complications of intratumoral therapy



Study endpoints[2,3]

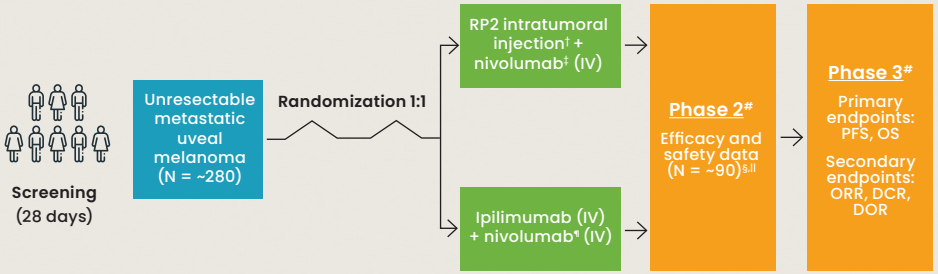
Key primary endpoints

- OS, PFS

Select secondary endpoints

- Safety
- Overall response rate (ORR)
- Disease control rate (DCR)
- Duration of response (DOR)

REVEAL study design[2,3]



†RP2 dose 1: up to 10 mL of RP2 at 1 x 10^6 PFU/mL IT injected; dose ≥2: up to 10 mL of RP2 at a concentration of 1 x 10^7 PFU/mL IT Q2W for a total of up to 8 doses; additional courses: up to 10 mL of RP2 at a concentration of 1 x 10^7 PFU/mL IT Q2W, up to 8 doses.

‡Starting with second dose of RP2, 240 mg IV Q2W for 8 doses, then 480 mg IV Q4W or 240 mg IV Q2W (Investigator's discretion) for up to 2 years from the first dose.

¶Ipilimumab 3 mg/kg IV Q3W for 4 doses; nivolumab 1 mg/kg Q3 for 4 doses, then 480 mg IV Q4W or 240 mg IV Q2W (Investigator's discretion) for up to 2 years from the first dose.

§Safety will be assessed primarily by AEs and laboratory abnormalities; physical examination findings, ECOG performance status, and vital signs will also be monitored and assessed.

||Efficacy and safety will be evaluated by independent data monitoring committee.

#During screening and at each follow-up tumor assessment, radiographic imaging as well as physical measurements with photography (as applicable) will be used to determine dosing volumes and to assess changes in injected tumor size. Overall, tumor response will be assessed 12 weeks from the date of randomization and then every 12 weeks (±7 days) thereafter until initiation of new anticancer therapy, confirmed disease progression, the patient dies, or withdraws from the study. Tumor assessments may also be conducted as needed by the Investigator for standard medical management.

AE, adverse event; aPTT, activated partial thromboplastin time; CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; HLA, human leukocyte antigen; ICI, immune-checkpoint inhibitor; IT, intratumoral; IV, intravenous; LDH, lactate dehydrogenase; PFU, plaque-forming unit; PT, prothrombin time; PTT, partial thromboplastin time; Q2W, once every 2 weeks; Q3W, once every 3 weeks; Q4W, once every 4 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; ULN, upper limit of normal.

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