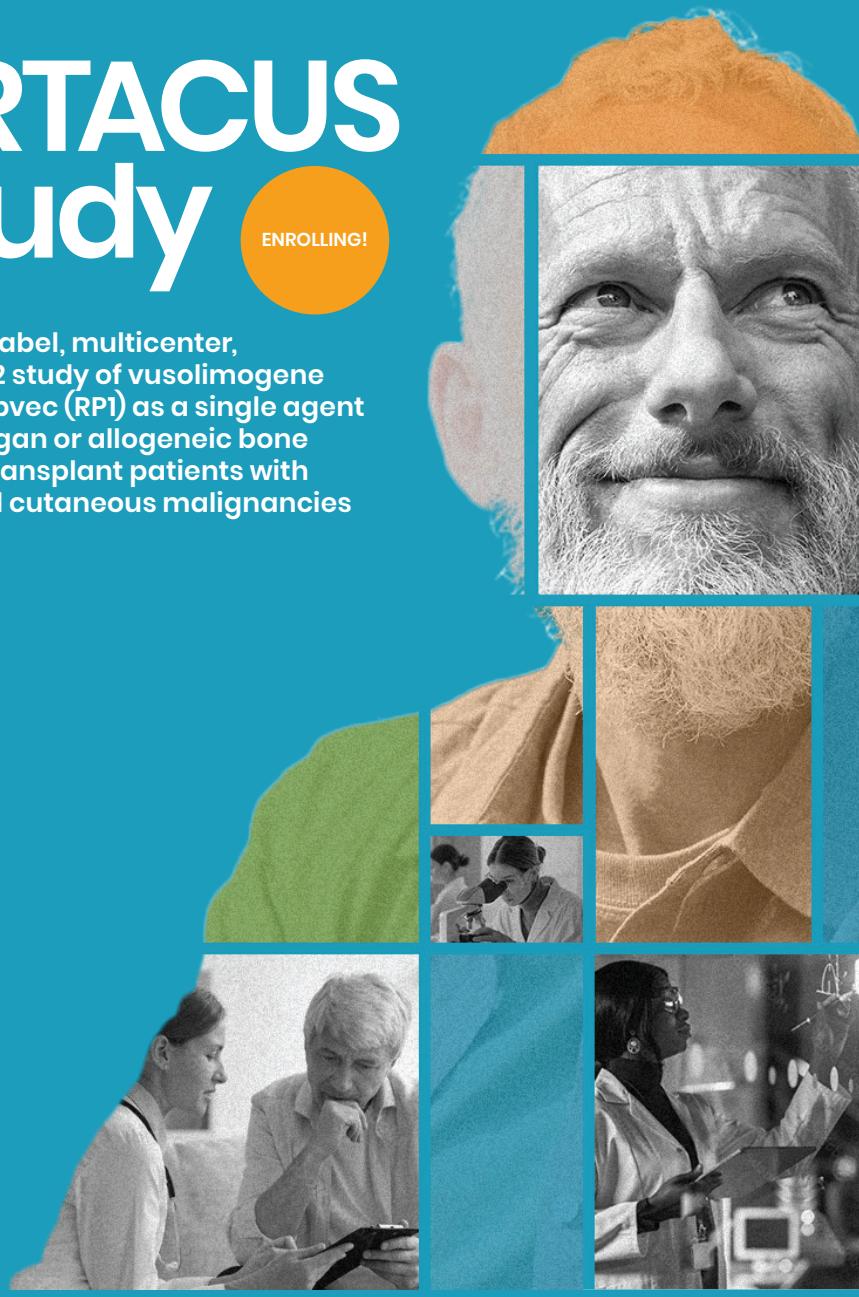
RP1

ARTACUS Study

ENROLLING!

An open-label, multicenter, phase 1B/2 study of vusolimogene oderparepvec (RP1) as a single agent in solid organ or allogeneic bone marrow transplant patients with advanced cutaneous malignancies



Important: Vusolimogene oderparepvec (RP1) is an investigational therapy and its use 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.

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USA-RP1-MED-0011

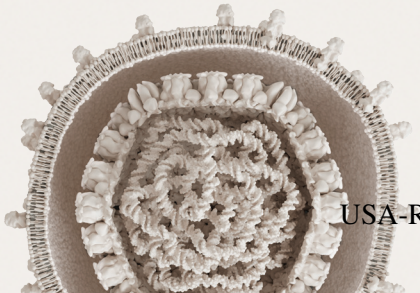
ARTACUS Study Overview

Transplant recipients with cutaneous malignancies lack effective treatment options beyond surgery, radiation therapy, chemotherapy, and targeted therapies. Data on the safety and efficacy of checkpoint inhibitors (anti-PD-1 and anti-CTLA-4) in treating cutaneous malignancies among transplant recipients are scarce, despite reports of improved cancer outcomes, there is an associated risk of allograft rejection. ARTACUS aims to assess if treatment with RP1 can help resolve cutaneous tumors while assessing its safety and tolerability, including preventing graft failure.[1]

ClinicalTrials.gov ID[2]	**NCT04349436**
Tumor type[1,2]	**Recurrent, locally advanced CSCC**
Intervention[1,2]	**RP1**
Estimated enrollment[1,2]	**65**

Key inclusion criteria[1,2]

- Aged ≥18 years, male or female
- Solid organ or allogeneic hematopoietic cell transplant patients with recurrent, locally advanced, cutaneous malignancies including CSCC
- Patients must have disease progression following a local resection and/or prior radiation and have received no more than 1 prior systemic therapy
- Stable allograft
- At least 1 measurable and injectable lesion (tumor of ≥1 cm in longest diameter or ≥1.5 cm in shortest diameter for lymph nodes)
- Patients for whom surgical treatment of lesions is contraindicated or the patient refuses surgery and/or radiation
- ECOG performance status ≤1
- No prior oncolytic immunotherapy



Study endpoints[1,2]

Key primary endpoints

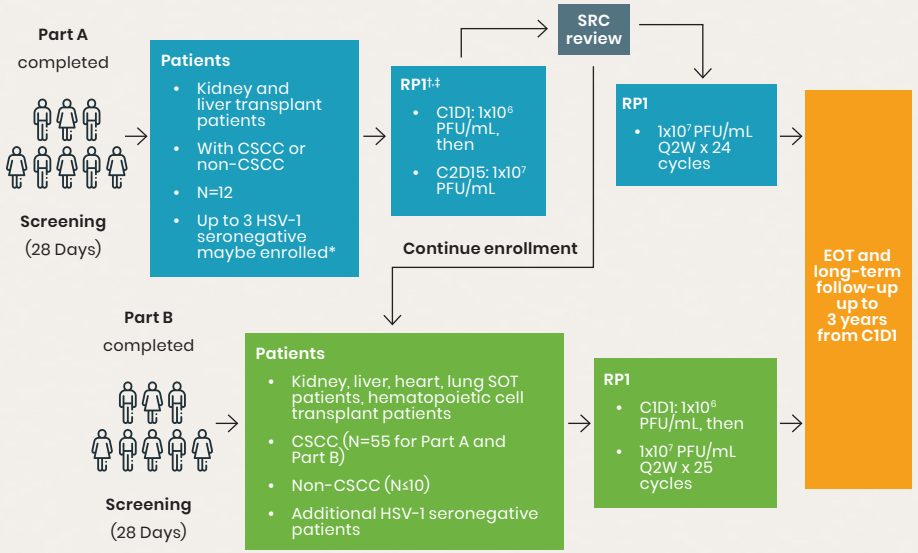
- Objective response rate (ORR)
- Safety and tolerability

Select secondary endpoints

- Duration of response (DOR)
- Complete response (CR)
- Progression-free survival (PFS)
- Overall survival (OS)

ARTACUS study design[1]

Patients will be screened for up to 4 weeks, followed by a 52-week treatment period, and up to 3 years of follow-up period from the date of the first dose of RP1.



*After 3 seronegative patients were enrolled, safety in this population was assessed by SRC, who approved continued enrollment of seronegative patients.

†The treatment period is up to 52 weeks (26 cycles); 1 cycle/2 weeks.

‡RP1 is administered via direct or ultrasound-guided IT injection into superficial, cutaneous, subcutaneous, or nodal solid tumors. Deep visceral solid organs or nonsolid tumors (e.g., malignant pleural effusions, malignant ascites, cerebral spinal fluid); solid tumors in the brain, bone, or spinal cord; or tumors in transplanted organs are not eligible for RP1 injection.

C: cycle; CSCC: cutaneous squamous cell carcinoma; CTLA-4: cytotoxic T-lymphocyte antigen-4; D: day; ECOG: Eastern Cooperative Oncology Group; EOT: end of treatment; HSV-1: herpes simplex virus 1; IT: intratumoral; PD-1: programmed cell death protein 1; PFU: plaque-forming unit; Q2W: every 2 weeks; RP1: vusolimogene oderparepvec; SOT: solid organ transplantation; SRC: safety review committee.

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ARTACUS study sites

If you have a potential patient who may qualify for the clinical trial, please consider reaching out to one of the institutions listed below.

State	City	Institute
Arizona	Phoenix	Medical Dermatology Specialists
California	La Jolla	University of California, San Diego, Moores Cancer Center
	Los Angeles	University of California, Los Angeles, Hematology/Oncology
	San Francisco	University of California San Francisco, Helen Diller Family Comprehensive Cancer Center Cutaneous Oncology
Colorado	Aurora	University of Colorado Hospital, Anschutz Medical Pavilion
Florida	Miami	University of Miami, Sylvester Comprehensive Cancer Center
	Tampa	Moffitt Cancer Center
Illinois	Chicago	University of Chicago
New York	Victor	Rochester Dermatologic Surgery
North Carolina	Durham	Duke University
Ohio	Cincinnati	University of Cincinnati Medical Center
	Columbus	Ohio State University Comprehensive Cancer Center
Pennsylvania	Pittsburgh	University of Pittsburgh Medical Center, Hillman Cancer Center
Texas	Houston	MD Anderson Cancer Center

Need more information?

Scan to view additional details on ClinicalTrials.gov

Contact Replimune's clinical trial team if you have questions. You can call **+1 (781) 222 9570** or email **clinicaltrials@replimune.com**

References:

1. ARTACUS Clinical Trial Protocol Amendment 6-13 Jan 2023 (Data on file).
2. A Phase 1B/2 Study of RP1 in Solid Organ Transplant Patients With Advanced Cutaneous Malignancies (ARTACUS). ClinicalTrials.gov NCT04349436. Updated March 1, 2024. Accessed April 26, 2024. https://www.clinicaltrials.gov/study/NCT04349436?term=ARTACUS&rank=1

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