



Replimune Announces TUDRIQEV™ Now Available in the U.S. for Advanced Melanoma

October 1, 2026

ReplimuneConnect Plus a comprehensive program that provides dedicated support and resources to help eligible patients access TUDRIQEV in the U.S. now live

WOBBURN, Mass., Oct. 01, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a commercial stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that TUDRIQEV™ (vusolimogene oderparepvec-wtpg) is now commercially available in the United States. TUDRIQEV is indicated in combination with nivolumab for the treatment of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

TUDRIQEV received accelerated approval from the U.S. Food and Drug Administration in early August. Beginning today, healthcare providers can order TUDRIQEV for next day delivery.

"With TUDRIQEV now available, we have reached a critical milestone in bringing this therapy to patients with advanced melanoma who have been waiting for a new option," said Sushil Patel, Ph.D., Chief Executive Officer of Replimune. "I'm deeply proud of our team, who moved with urgency to put the infrastructure and comprehensive patient support services in place so that healthcare providers can access this therapy with next day delivery when their patients need it."

Administration

TUDRIQEV is administered by direct intratumor injection into superficial, deep, and/or visceral lesions, with imaging guidance used for deep or visceral lesions. It is given once every two weeks for eight consecutive doses, with the dose based on tumor size; a lower concentration is used for the first dose and a higher concentration for subsequent doses. Nivolumab is administered intravenously beginning at week three. Please see the full Prescribing Information for complete dosing, preparation, handling, and administration instructions.

Clinical Data Supporting Approval

The accelerated approval was based on the registrational anti-PD-1-failed melanoma cohort of the IGYTE trial, which enrolled 140 patients. Among the 91 efficacy-evaluable patients with at least one non-injected lesion, TUDRIQEV plus nivolumab achieved an objective response rate of 24.2% (95% CI: 15.8, 34.3) with a median duration of response of 14.1 months (95% CI: 10.7, not reached).

A confirmatory Phase 3 trial, IGYTE-3 (NCT06264180), is ongoing.

ReplimuneConnect Plus Patient Support Program

Replimune is committed to helping eligible patients in the U.S. access treatment with TUDRIQEV. ReplimuneConnect Plus is a comprehensive program that provides information and support on access, reimbursement, and financial assistance for eligible patients who are prescribed TUDRIQEV, including benefits investigation, co-pay assistance for eligible commercially insured patients, referrals to independent foundations, and case manager support.

Patients, caregivers, and healthcare providers can learn more and enroll at replimuneconnectplus.com or by calling 1-833-775-7587, Monday through Friday from 8 AM to 8 PM ET.

About Melanoma

Melanoma is the fifth most common cancer, with approximately 105,000 new cases estimated in the U.S. in 2025, and the most lethal form of skin cancer, accounting for nearly 8,500 deaths annually. Standard of care includes immune checkpoint blockade, to which approximately half of patients will not respond or will progress after treatment. For patients who progress following anti-PD-1 therapy, treatment options are limited.

About TUDRIQEV™ (vusolimogene oderparepvec-wtpg)

TUDRIQEV is a genetically modified herpes simplex virus type 1 (HSV-1) oncolytic viral therapy that encodes a fusogenic glycoprotein derived from gibbon ape leukemia virus with the R sequence deleted (GALV-GP-R-) and human granulocyte macrophage colony-stimulating factor (GM-CSF). The genes encoding the HSV-1 neurovirulence factor ICP34.5 and the ICP47 inhibitor of antigen presentation are deleted. TUDRIQEV preferentially replicates within tumors, leading to tumor lysis and release of tumor and viral antigens. In combination with nivolumab, TUDRIQEV may promote an anti-tumor immune response in the anti-PD-1-resistant setting. For more information, visit [Tudrigev.com](https://tudrigev.com).

INDICATION

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unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

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IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Accidental Exposure to TUDRIQEV: Healthcare providers, caregivers, close contacts, pregnant women, newborns, and patients should avoid direct contact with injected tumors, dressings, or bodily fluids of patients. Should accidental exposure occur, clean the affected area.

Herpetic Infection or Reactivation: Assess and treat suspected herpetic lesions as clinically warranted.

Visceral Injury: Monitor patients for signs and symptoms of visceral injury during and after TUDRIQEV administration and manage accordingly.

Adverse Reactions

Serious adverse reactions occurred in 35% of 140 patients who received TUDRIQEV in combination with nivolumab, including 2 patients each with arthralgia, hypophysitis, immune-mediated enterocolitis, and pyrexia. Adverse reactions leading to permanent discontinuation of TUDRIQEV occurred in 2.9% of 140 patients and were 1 each of amylase increased, lipase increased, myocarditis, and pneumonitis.

The most common non-laboratory adverse reactions (incidence >10%) are fatigue, pyrexia, chills, musculoskeletal pain, nausea, diarrhea/colitis, injection site reaction, headache, cough, influenza-like illness, vomiting, pruritus, arthralgia, asthenia, constipation, decreased appetite, dizziness, skin/superficial infection, and dyspnea.

Drug Interactions

Antivirals: Delay TUDRIQEV administration for 72 hours.

Use in Specific Populations

Females and Males of Reproductive Potential: Advise females of reproductive potential, and males with a female partner of reproductive potential, to use effective contraception during TUDRIQEV treatment and for 90 days after the last dose.

Please report any adverse event or product quality complaint related to a Replimune product by calling 1-877-375-0095. You may also contact the FDA directly at www.fda.gov/medwatch or 1-800-FDA-1088.

Please see full Prescribing Information, including Patient Information, at www.replimune.com/medicines. Please also refer to the full Prescribing Information for nivolumab.

About Replimune

Replimune Group, Inc., headquartered in Woburn, Massachusetts, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel oncolytic immunotherapies. TUDRIQEV is the company's first commercially available product. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone intended to maximize immunogenic cell death and induce a systemic anti-tumor immune response. For more information, visit www.replimune.com and follow the company on LinkedIn and X.

Forward-Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs, sufficiency of any resulting data), our ability to execute on our strategic or financial initiatives, and potential commercial viability, and potential reimbursement and utilization of TUDRIQEV involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Our ability to maintain TUDRIQEV's accelerated approval and to continue commercialization of TUDRIQEV may be contingent on verification of clinical benefit in a confirmatory trial(s). Other forward looking statements may be identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited experience in commercializing products for sale, our ability to successfully verify the clinical benefit of TUDRIQEV in our ongoing confirmatory Phase 3 trial, IGNYTE-3, our ability to meet our product manufacturing goal, the timing and scope of future regulatory approvals, the availability of combination therapies needed to conduct our clinical trials, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, the impact of political and global macro factors and military conflicts, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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