Replimune Announces FDA Accelerated Approval of TUDRIQEVTM in Combination with Nivolumab for Unresectable Advanced Cutaneous Melanoma After Progression on an anti-PD-1 Based Regimen

August 6, 2026

Broad label to address high unmet need in advanced melanoma

Replimune will host conference call on August 6, 2026 at 4:30 p.m. ET.

WOBURN, Mass., Aug. 06, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a commercial stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval for TUDRIQEV™ (vusolimogene oderparepvec-wtpg), previously referred to as RP1, in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression on an anti-PD-1 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 on verification of clinical benefit in a confirmatory trial(s).

The IGNYTE trial enrolled 140 patients with 91 patients with at least one non-injected lesion included in the efficacy-evaluable population. In this population, TUDRIQEV plus nivolumab achieved an objective response rate (ORR) of 24.2%, with a median duration of response of 14.1 months. Treatment was well tolerated with mostly mild-to-moderate adverse events. The patient population included patients with Stage 4 disease (80%), prior anti-PD-1 adjuvant treatment (13%), PD-L1 negative status (54%), lung (45%) and liver lesions (24%). The IGNYTE study data were published in the *Journal of Clinical Oncology* and are available here.

“This is a transformative moment for Replimune, marking years of pioneering research to bring TUDRIQEV to patients desperately in need of new treatment options for advanced melanoma,” said Sushil Patel, Ph.D., CEO of Replimune. “We are deeply grateful to the melanoma community, including patients and investigators who participated in the clinical trial, for their tremendous support of this approval. We also would like to thank the FDA for recognizing the urgency to get this therapy to patients. Replimune is now focused on critical activities to deliver TUDRIQEV to as many patients as possible.”

There are limited treatment options for advanced melanoma, and more than half of patients experience progression within six months of treatment on immune checkpoint inhibitors like anti-PD-1 therapy. These patients face a poor prognosis, with a median overall survival of less than one year following progression.

“Advanced melanoma patients have few options after anti-PD-1 therapy and face high morbidity and poor survival outcomes,” said Michael K. Wong, MD, PhD, primary investigator of the IGNYTE study and Former Physician in Chief and Professor of Oncology at Roswell Park Comprehensive Cancer Center in Buffalo, NY. “With the approval of TUDRIQEV, we have a potent oncolytic immunotherapy that can be used in a broad population, including BRAF-naïve or pretreated, and adjuvant relapsed patients. Importantly, the therapy in combination with nivolumab drives immune activation with a favorable risk-benefit profile and can be injected into superficial and visceral lesions.”

“The approval of RP1 in combination with nivolumab is a meaningful step forward for patients with advanced melanoma who have failed to benefit from immunotherapy,” said Sam Guild, President of AIM at Melanoma. “Every year, more than 8,500 people die of melanoma in the U.S., and new treatment options are urgently needed.”

TUDRIQEV combined with nivolumab was well-tolerated. The most common (incidence ≥ 10%) adverse reactions in patients treated with TUDRIQEV combined with nivolumab were nausea, diarrhea, vomiting, constipation, decreased appetite, abdominal pain, fatigue, pyrexia, chills, injection site reaction, influenza like illness, infections, musculoskeletal pain, arthralgia, headache, dizziness, cough, dyspnea, rash, pruritic and hemorrhage.[1] Most treatment-related adverse reactions were grade 1 and 2 and transient.[1] There were no grade 4 or 5 common adverse events. See additional Important Safety Information below.

TUDRIQEV is administered via direct intratumor injection into superficial and deep and/or visceral lesions[1]. For deep/visceral tumors, administration is guided by imaging technology.[1] The recommended dose of TUDRIQEV is based on tumor size.[1]

To verify the clinical benefit of TUDRIQEV, a confirmatory Phase 3 trial, IGNYTE-3, is ongoing and assessing TUDRIQEV in combination with nivolumab (NCT06264180). For additional information about the trial, please visit **https://replimune.com/clinical-trials/ignyte-3/**.

Replimune is committed to helping patients in the U.S. with advanced melanoma gain access to treatment with TUDRIQEV. Eligible patients who are prescribed TUDRIQEV will have access to ReplimuneConnect *Plus*, a comprehensive program offering information on access, reimbursement and financial support.

Webcast Details
Replimune will host a webcast featuring members from the management team to discuss today's developments at 4:30 p.m. ET on Thursday, August 6, 2026.

Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 therapy includes treatment with immune checkpoint blockade, to which approximately half of patients will not respond or will progress after treatment. Melanoma is considered advanced when the cancer spreads beyond the primary tumor to other parts of the body.

About IGNYTE
IGNYTE (NCT03767348) is an open-label, multicenter Phase 1/2 study evaluating the safety and efficacy of vusolimogene oderparepvec as monotherapy or in combination with nivolumab in adult patients with advanced solid tumors, including a registrational cohort of patients with advanced melanoma with confirmed progression on an anti-PD-1 containing regimen treated with vusolimogene oderparepvec plus nivolumab.

The anti-PD-1 failed melanoma registrational cohort included 140 patients who received vusolimogene oderparepvec plus nivolumab after confirmed progression while being treated for at least eight weeks with anti-PD-1 based therapy, with or without anti-CTLA-4. Of the 140 patients, 91 patients with at least one noninjected lesion were included in the efficacy-evaluable population.

About TUDRIQEV™ (vusolimogene oderparepvec-wtpg)
TUDRIQEV (vusolimogene oderparepvec-wtpg) 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 transporter associated with antigen presentation inhibitor ICP47 are deleted from TUDRIQEV. TUDRIQEV preferentially replicates within the tumor leading to tumor lysis, release of tumor and viral antigens, proinflammatory molecules, and infiltration of T cells. The GALV-GP-R– expressed by TUDRIQEV increases direct tumor killing and the GM-CSF expressed by TUDRIQEV is intended to activate and mature dendritic cells and monocytes. In the anti-PD-1 resistant setting, TUDRIQEV and nivolumab in combination may promote anti-tumor immune response.

INDICATION
TUDRIQEV (vusolimogene oderparepvec-wtpg) 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).

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 TUDRIQEV discontinuation occurred in 2.9% of 140 patients and were 1 each of amylase increased, lipase increased, myocarditis, and pneumonitis.

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.

Special 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. If

you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088.**

Please click here for full Prescribing Information, including Patient Information.

About Replimune
Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel oncolytic immunotherapies, including the Company's first commercially available product TUDRIQEV™ (vusolimogene oderparepvec-wtpg), approved under accelerated approval by the U.S. Food and Drug Administration in combination with nivolumab for the treatment of adults with advanced melanoma who experienced disease progression on a PD-1 antibody-based regimen. 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. Upon intratumor injection, RPx causes direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens, alteration of the tumor microenvironment, and when dosed in combination with an immune checkpoint inhibitor immunotherapy, it may ignite a systemic anti-tumor response. The RPx product candidates are expected to be synergistic with most established and experimental cancer treatment modalities, leading to the versatility to be developed alone or combined with a variety of other treatment options. For more information on Replimune, please visit **www.replimune.com** and follow us on social media at **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), regulatory applications and related submission contents and timelines, the timelines or outcomes related to litigation, including any rehearings or appeals of decisions in any such proceedings, and our ability to execute on our strategic or financial initiatives, our estimates regarding future expenses, capital requirements and needs for additional financing, 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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[i] TUDRIQEV Prescribing Information. Last updated: 08/26.