TUDRIQEV™

(vusolimogene oderparepvec-wtpg) 1 mL for injection

NOW APPROVED

FIRST AND ONLY ONCOLYTIC VIRAL THERAPY USED WITH NIVOLUMAB

as an immunotherapy regimen
for adults with advanced melanoma

TUDRIQEV (pronounced “TOO-drih-kev“)

Indication

TUDRIQEV Is:

- Used with nivolumab to treat adults with advanced melanoma who have previously received an anti-PD-1-based regimen.

Please see Important Safety Information on pages 8–9 and read the TUDRIQEV™ Patient Medication Information. Please see full Prescribing Information.

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HCP = healthcare provider

How TUDRIQEV™ works

- TUDRIQEV is an oncolytic viral therapy based on a genetically modified herpes virus that treats cancer by directly killing tumor cells and activating certain cells of the immune system.
- TUDRIQEV is injected directly into cancer tumors found on your skin or in your body. It works by directly killing cancer cells and in combination with nivolumab may promote an immune response.
- HSV-1 is the virus that causes common cold sores.
- If you develop a cold sore that you think may be due to exposure to TUDRIQEV, seek medical advice.
  - Herpetic infections or reactivations were observed in the clinical trials. Promptly report any suspected cold sores or herpetic infection (herpes simplex virus, type 1), such as blisters or sores on any part of your body. Contact your doctor or call Replimune Medical Information at **1-877-375-0095**. You will be provided a free swab sample collection kit to be returned for testing.
- Tell your doctor if you have received antiviral medicine such as acyclovir. TUDRIQEV might not be effective if given within 72 hours of these medicines.

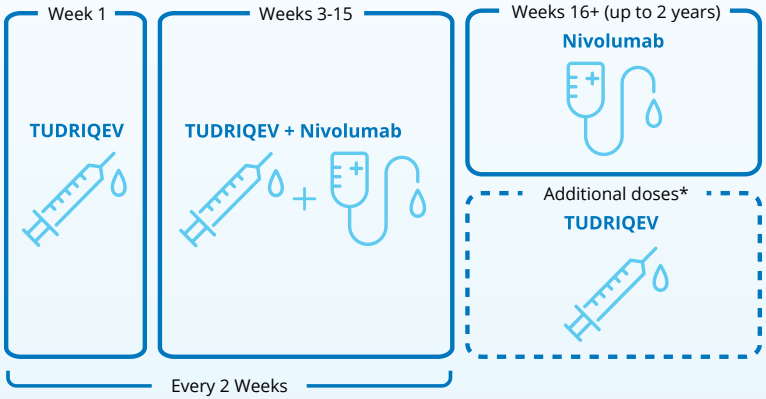
How TUDRIQEV™ is administered

- TUDRIQEV is given by your healthcare provider and is not self-administered. After injection, keep the injection site(s) covered for at least 48 hours.
- TUDRIQEV is injected with a needle/syringe directly into your tumor(s) and is NOT given as an intravenous (IV) injection.
- Your healthcare provider will inject tumors that are visible or palpable (can be felt by touch) or tumors inside your body in specific organs such as your liver, kidney, or lung (known as deep or visceral tumors).
- Your healthcare provider may use imaging techniques such as ultrasound or CT scan (Computed Tomography scan) to guide the needle's injection especially when treating deep or visceral tumors.

TUDRIQEV DOSING AND SCHEDULE

Read the **TUDRIQEV™ Patient Medication Information** before you start receiving TUDRIQEV and before each injection.

TUDRIQEV is used in combination with nivolumab (OPDIVO®) starting at Week 3. Your healthcare provider will use nivolumab according to its prescribing information.



* At your healthcare provider's discretion, you may receive additional doses of TUDRIQEV every 2 weeks. These doses may be given with nivolumab or, if nivolumab is stopped because of side effects, TUDRIQEV may be given on its own.

IGNYTE: The TUDRIQEV™ Clinical Trial

TUDRIQEV in combination with nivolumab was studied in 140 patients with advanced melanoma. All patients experienced disease progression while receiving an anti-PD-1 (a type of immunotherapy) based regimen.

Overall,

24% **(22 of 91 patients) responded to treatment**

Among patients who responded to treatment, half continued to respond for at least

14 months

More than 8 out of 10 patients maintained their response for at least 6 months, and more than half maintained their response for at least 1 year

What are possible side effects?

The most common side effects of TUDRIQEV with nivolumab treatment include:

- Tiredness
- Chills
- Diarrhea
- Infection
- Joint or muscle pain
- Fever
- Nausea
- Injection Site Reactions (redness, pain, or swelling)
- Flu-like illness or symptoms

These are not all of the possible side effects of TUDRIQEV. Call your health care provider if you have side effects that worsen or do not go away. You may also report side effects to FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Herpetic infections or reactivations were observed in the clinical trials. Promptly report any suspected cold sores or herpetic infection (herpes simplex virus, type 1), such as blisters or sores on any part of your body. Contact your doctor or call Replimune Medical Information at **1-877-375-0095**. You will be provided a free swab sample collection kit to be returned for testing.

Before taking TUDRIQEV™, tell your healthcare provider about all of your medical conditions and medications.

Special Population

Both men and women should use effective birth control during treatment and for 90 days after the last TUDRIQEV injection. Talk to your healthcare provider for more information.

Tell your health care provider:

- If you are breastfeeding or plan to breastfeed. You should not breastfeed during your treatment and for 90 days after your last injection of TUDRIQEV.
- If you are pregnant or plan to become pregnant. For women, your healthcare provider should advise you to take a pregnancy test before starting your TUDRIQEV treatment.
- If you become pregnant during your TUDRIQEV treatment.
- About all the medications you take including prescription and over-the-counter medicines such as antivirals, vitamins, and herbal supplements.

What should I avoid while receiving TUDRIQEV™?

- Avoid touching or scratching the injection sites and dressing to prevent the transfer of TUDRIQEV. You or your caregiver should always wear gloves when replacing or changing your injection site dressings.

If you receive injections of TUDRIQEV into tumors in your liver, lung or other organs:

- Injections of TUDRIQEV into tumors in your liver, lung or other organs may cause injury that requires further monitoring or treatment.

TUDRIQEV may cause serious side effects.

Call your healthcare provider right away if you develop any of the following signs and symptoms:

- Joint pain
- Headache, vision changes, dizziness or tiredness, which may be signs of inflammation of the pituitary gland
- Abdominal pain, cramping, diarrhea, nausea
- Fever

TUDRIQEV™ Indication & Important Safety Information

Indication

TUDRIQEV is used with nivolumab to treat adults with advanced melanoma who have previously received an anti-PD-1-based regimen.

Patient Important Safety Information

Warnings:

- Avoid touching or scratching the injection sites and dressing to prevent the transfer of TUDRIQEV. You or your caregiver should always wear gloves when replacing or changing your injection site dressings.
- TUDRIQEV may cause a new or a reactivation of the common cold sore (herpes simplex virus, type 1). If you develop a cold sore after treatment with TUDRIQEV, contact your doctor to provide a swab for testing. You may also call TUDRIQEV Medical Information for guidance at **1-877-375-0095**.
- Injections of TUDRIQEV into tumors in your liver, lung or other organs may cause injury that requires further monitoring or treatment.

Serious side effects:

TUDRIQEV may cause serious side effects. Call your healthcare provider right away if you develop any of the following signs and symptoms:

- Joint pain
- Headache, vision changes, dizziness or tiredness, which may be signs of inflammation of the pituitary gland
- Abdominal pain, cramping, diarrhea, nausea
- Fever

Drug Interactions

Tell your doctor if you have received antiviral medicine such as acyclovir. TUDRIQEV might not be effective if given within 72 hours of these medicines.

Special Population

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Tell your health care provider:

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- If you are pregnant or plan to become pregnant. For women, your healthcare provider should advise you to take a pregnancy test before starting your TUDRIQEV treatment.
- If you become pregnant during your TUDRIQEV treatment.
- About all the medications you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Common Side Effects:

The most common side effects of TUDRIQEV with nivolumab treatment include:

- Tiredness
- Chills
- Diarrhea
- Infection
- Joint or muscle pain
- Fever
- Nausea
- Injection Site Reactions (redness, pain, or swelling)
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These are not all of the possible side effects of TUDRIQEV. Call your health care provider if you have side effects that worsen or do not go away. You may also report side effects to FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Directions for Use

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Notes

SIGN UP FOR MORE INFORMATION ABOUT TUDRIQEV™
Visit TUDRIQEV.com

Replimune®
connect*Plus*

ReplimuneConnect *Plus* is a patient support program designed to help individuals access and get support on TUDRIQEV. Patient Access Specialists offer guidance on insurance, co-pay, and assistance programs to make navigating the process easier for patients.

Ask your doctor about enrollment in ReplimuneConnect *Plus*. For more information about financial support options, please call ReplimuneConnect *Plus* at
1-833-775-7587, Monday–Friday, 8 AM–8 PM ET

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TO LEARN MORE, PLEASE VISIT

TUDRIQEV.COM

Talk to your healthcare team and read the **TUDRIQEV™ Patient Medication Information** before you start receiving TUDRIQEV and before each injection.

Please see full Prescribing Information.

Replimune®

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