

FDA APPROVED

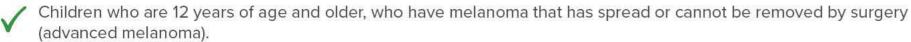
# DISCOVER A TREATMENT

that can help energize the immune system to fight advanced melanoma

#### What is Opdualag?

Opdualag is a premixed combination of nivolumab and relatlimab that is prepared and given through intravenous (IV) infusions. Opdualag is a prescription medicine used to treat:





It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or in children 12 years and older weighing less than 88 pounds (40 kg) or for the treatment of any other cancers.



Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guide for Opdualag in the links below.



Opdualag™ is a medicine that may treat melanoma that has spread or cannot be removed by surgery by working with your immune system. Opdualag can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. Some of these problems can sometimes become severe and can lead to death.



Please see additional **Important Facts** for Opdualag.





















# Opdualag can help energize your immune system by combining 2 different immunotherapies into 1 medicine



Your immune system has

T cells that attack cancer cells.



Tired T cell

But T cells can
get tired.



Nivolumab



WHY

**OPDUALAG** 





**Energized T cell** 

Energized T cells can help get your immune system ready to attack cancer.

This is a general example of how Opdualag works. Each patient is different and clinical results may vary.

Opdualag can cause your T cells to attack healthy cells contained within organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check for these problems during treatment.

Visit www.Opdualag.com for more information.



Please see <u>Important Facts</u> for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.

### SELECT IMPORTANT SAFETY INFORMATION

## What are the serious side effects of Opdualag™?

Opdualag can cause serious side effects any time during and after treatment. A **serious side effect** is a side effect that can sometimes become life-threatening and can lead to death. Serious side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.



Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- lung problems
- · intestinal problems
- liver problems
- hormone gland problems
- kidney problems
- skin problems
- heart problems

Immune system-related side effects























### Opdualag can help energize your immune system by combining 2 different immunotherapies into 1 medicine



Cancer cell

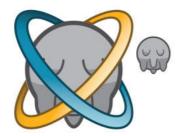
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#### **Opdualag**



Relatlimab

WHY

**OPDUALAG** 

Nivolumab

Two immunotherapies connect to some T cells and work in sync to energize them.



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#### can also happen in other organs and tissues with Opdualag, including:

- · brain and nerve problems
- eye or vision problems
- · muscle problems
- blood problems

#### Severe infusion reactions may include:

- chills or shaking
- · itching or rash
- flushing
- · shortness of breath
- dizziness
- feeling like passing out
- fever
- back or neck pain



Tell your healthcare team right away if you get these symptoms during or after an infusion of Opdualag.

#### **Stem Cell Transplant Complications**

You may experience complications if you receive donor stem cells (allogeneic stem cell transplant) before or after treatment with Opdualag. These complications can be severe and can lead to death.





















### Opdualag can help energize your immune system by combining 2 different immunotherapies into 1 medicine



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Relatlimab

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Please see Important Facts for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.

Your healthcare team will monitor you for signs of complications if you have an allogeneic stem cell transplant.

#### What are the most common side effects?

The most common side effects of Opdualag include:

- muscle and bone pain
- tiredness
- decreased red blood cell and white blood cell counts
- · increased liver function test results
- rash
- itching
- diarrhea
- · decreased salt (sodium) in your blood

These are not all the possible side effects.



#### Talk to your healthcare team for more information. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.



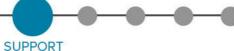


















# Opdualag can help energize your immune system by combining 2 different immunotherapies into 1 medicine



T cell Cancer cell

Your immune system has T cells that attack cancer cells.



But T cells can get tired.

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#### Opdualag



Relatlimab

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Please see additional **Important Facts** for Opdualag.



















**INFORMATION** 



# Two kinds of medicine, two times as long without advanced melanoma spreading

In a **clinical trial** of 714 patients with advanced melanoma, 355 were given Opdualag and 359 were given nivolumab alone, a standard treatment. Those who received Opdualag saw their melanoma remain stable (known as "stable disease") for more than two times as long.

Patients on Opdualag lived more than **2X longer** without melanoma growing, spreading, or getting worse.



#### **Opdualag**

(nivolumab and relatlimab-rmbw)

10.1 months

Standard Treatment (nivolumab)

4.6 months

In the primary analysis at 13.2 months, half of the patients on **Opdualag** went 10.1 months without melanoma growing, spreading, or getting worse. In the primary analysis at 13.2 months, half of the patients on **standard treatment** went 4.6 months without melanoma growing, spreading, or getting worse.

The median follow-up analysis at 19.3 months was consistent with the earlier (primary) analysis at 13.2 months. At the 13.2-month primary analysis, Opdualag reduced the risk of cancer spreading, growing, or getting worse by 25% compared to nivolumab alone.

Opdualag may not work for everyone. Individual results may vary.



Talk to your healthcare team to find out if Opdualag is right for you.

#### What is a clinical trial?

A clinical trial is a type of research study that tests how well new medical approaches work in people.

Visit www.Opdualag.com for more information.



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Immune system-related side effects

can also happen in other organs













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**Learn More** 







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HOME





















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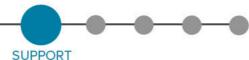






















#### **CONTINUE EVERY 4 WEEKS**

Work with your healthcare provider to determine how many treatments you need based on how your body reacts to the treatment.



Opdualag is a premixed combination of 2 medicines given through an intravenous (IV) infusion.



You and your healthcare provider should discuss the best place to get your infusions, whether it's your doctor's office, an infusion center, or a local hospital.

#### What is an IV infusion?

An IV infusion is when medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.



Your healthcare provider will do blood tests to check you for side effects.



If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

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#### SELECT IMPORTANT SAFETY INFORMATION

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Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- lung problems
- · intestinal problems
- liver problems
- · hormone gland problems
- · kidney problems
- skin problems
- heart problems

Immune system-related side effects can also happen in other organs





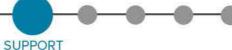
























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#### can also happen in other organs and tissues with Opdualag, including:

- brain and nerve problems
- eye or vision problems
- muscle problems
- blood problems

### **Severe infusion reactions** may include:

- chills or shaking
- itching or rash
- flushing
- · shortness of breath
- dizziness
- · feeling like passing out
- fever
- · back or neck pain



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#### **Stem Cell Transplant Complications**

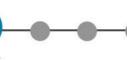
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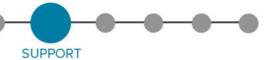
























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The most common side effects of Opdualag include:

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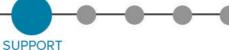
























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### Important Facts About Opdualag™ (nivolumab and relatlimab-rmbw)

This is a summary of important information that you need to know about Opdualag. Your healthcare team can work with you to help answer any questions you may have about this medication. Keep this information in a safe place so you can refer to it before and during your treatment.

Look out for the following icons as you read:





Call a healthcare provider right away



Helpful information to remember

#### What is Opdualag?

Injection for intravenous use | 480 mg/160 mg



Opdualag is a premixed combination of nivolumab and relatlimab that is prepared and given through intravenous (IV) infusions. Opdualag is a prescription medicine used to treat:

- ✓ Adults who have a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).
- Children who are 12 years of age and older, who have melanoma that has spread or cannot be removed by surgery (advanced melanoma).

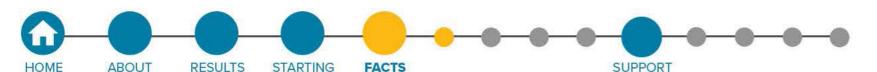
It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or in children 12 years and older weighing less than 88 pounds (40 kg) or for the treatment of any other cancers.

An IV infusion is when medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional – usually in the arm or hand.

#### What is the most important information I should know about Opdualag?

Opdualag can cause serious side effects any time during and after treatment. A **serious side effect** is a side effect that can sometimes become life-threatening and can lead to death. Serious side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

Get medical help right away if you develop any new symptoms or if they get worse. It may keep these problems from becoming more serious.











#### WHY OPDUALAG

STARTING ON OPDUALAG

IMPORTANT FACTS EDUCATION & SUPPORT



**Get medical help right away** if you develop any new symptoms or if they get worse. It may keep these problems from becoming more serious. Your healthcare team will check you for side effects during treatment, and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your healthcare team may need to delay or completely stop your treatment.

#### Immune system-related side effects

Opdualag is a medicine that may treat melanoma that has spread or cannot be removed by surgery by working with your immune system. Opdualag can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. Some of these problems can sometimes become severe and can lead to death.

This is a list of some possible immune system-related side effects of Opdualag. You may experience other side effects that are not listed. You may experience side effects anytime during treatment or even after treatment has ended.



Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

**ABOUT** 

**OPDUALAG** 

#### **Lung problems** — Things to look out for may include:

· new or worsening cough

· shortness of breath

· chest pain

#### Intestinal problems — Things to look out for may include:

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus

 severe stomach-area (abdominal) pain or tenderness

#### **Liver problems** — Things to look out for may include:

- yellowing of your skin or the whites of your eyes
- · severe nausea or vomiting

- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)

 bleeding or bruising more easily than normal

#### Hormone gland problems — Things to look out for may include:

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems

and boarthast

- weight gain or weight loss
- feeling more hungry or thirsty than usual
- · urinating more often than usual

- constipation
- your voice gets deeper
- · dizziness or fainting
- changes in mood or behavior, such as

darraand not drive initability as













#### **ABOUT OPDUALAG**

#### WHY **OPDUALAG**

#### STARTING ON **OPDUALAG**

#### **IMPORTANT FACTS**

**EDUCATION & SUPPORT** 

- rapid heartbeat
- · increased sweating
- extreme tiredness

- hair loss
- · feeling cold

decreased sex drive, irritability, or forgetfulness

- **Kidney problems** Things to look out for may include:
- · decrease in the amount of urine

- · blood in your urine
- swelling in your ankles

loss of appetite

- **Skin problems** Things to look out for may include:
- rash

skin blistering or peeling

itching

· painful sores or ulcers in the mouth or nose, throat, or genital area

· swelling in your ankles

- **Heart problems** Things to look out for may include:
- · new or worse chest pain

- · shortness of breath
- irregular heartbeat or feel like your heart is racing
- tiredness
- Immune system-related side effects can also happen in other organs and tissues with Opdualag™ (nivolumab and relatlimab-rmbw), including:
- **Brain and nerve problems** Things to look out for may include:
- confusion

sleepiness

- · changes in mood or behavior
- stiff neck

· memory problems

- balance problems

• tingling or numbness of the arms or legs

- **Eye or vision problems** Things to look out for may include:
- · double vision blurry vision

- · sensitivity to light
- eye pain

· changes in eyesight

**Muscle problems** — Things to look out for may include:

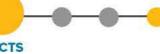


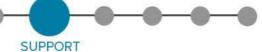






















#### ABOUT OPDUALAG

WHY OPDUALAG STARTING ON OPDUALAG

IMPORTANT FACTS EDUCATION & SUPPORT

 persistent or severe muscle pain or weakness muscle cramps

**Blood problems** — Things to look out for may include:

low red blood cells

bruising



Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms.

#### What are some other serious side effects of Opdualag?

#### Severe Infusion Reactions

Opdualag™ (nivolumab and relatlimab-rmbw) is given through intravenous (IV) infusions. The medicine is put directly into your bloodstream through a needle that a healthcare professional places in a vein, usually in your arm or hand.

Things to look out for during an infusion of Opdualag may include:

· chills or shaking

shortness of breath

fever

itching or rash

dizziness

· back or neck pain

flushing

· feeling like passing out



Tell your healthcare team right away if you get these symptoms during or after an infusion of Opdualag.

#### **Stem Cell Transplant Complications**

You may experience complications if you receive donor stem cells (allogeneic stem cell transplant) before or after treatment with Opdualag.

These complications can be severe and can lead to death. Your healthcare team will monitor you for signs of complications if you have an allogeneic stem cell transplant.











#### What are the most common side effects?

The most common side effects of Opdualag include:

· muscle and bone pain

· rash

 diarrhea · decreased salt (sodium) in your blood

tiredness

- decreased red blood cell and white blood cell counts
- · itching

These are not all the possible side effects.



Talk to your healthcare team for more information. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

increased liver function test results

#### What should I discuss with my healthcare team about pregnancy, birth control, and breastfeeding?



Talk to your healthcare team if:



You are pregnant or plan to become pregnant – Opdualag can harm your unborn baby

If you are able to become pregnant, your healthcare team should do a pregnancy test before you start receiving Opdualag. You should use an effective method of birth control during treatment and for at least 5 months after your last dose of Opdualag.



Talk to your healthcare team about birth control methods that you can use during this time.

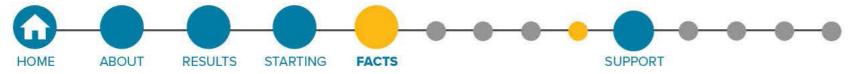


Tell your healthcare team right away if you become pregnant or think you are pregnant during treatment with Opdualag.



You are breastfeeding or plan to breastfeed

It is not known if Opdualag passes into your breast milk. Do not breastfeed during treatment with Opdualag and for 5 months after the last dose of Opdualag.











#### What should I discuss with my healthcare team before starting treatment?



(*nivolumab and relatlimab-rmbw)* Injection for intravenous use | 480 mg/160 mg

Talk to your healthcare team about all your health problems or concerns, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have had an organ transplant
- have had or plan to have a stem cell transplant that uses donor stem cells (allogeneic)
- · have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome



Tell your healthcare team about all the medicines you take, including:

- prescription medicines
- · over-the-counter medicines

- vitamins
- · herbal supplements

These are not all the topics you should discuss with your healthcare team. Ask your healthcare team about anything you may be unsure about before starting treatment.

#### **How will I receive Opdualag?**

Opdualag is a premixed prescription medication (12 mg/mL nivolumab and 4 mg/mL relatlimab) that is prepared and given as intravenous (IV) infusions by your healthcare team.



An IV infusion is when medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional – usually in the arm or hand.

#### Dosage:



Talk to your healthcare team to learn more about the dosing for Opdualag.

#### **Receiving Opdualag:**



IV infusion time is about 30 minutes, though actual time in clinic or place of infusion may vary.



Opdualag is usually given every 4 weeks. Your healthcare provider will decide how many treatments you will receive and do blood tests to













the arm or hand.

#### Dosage:



Talk to your healthcare team to learn more about the dosing for Opdualag.

#### **Receiving Opdualag:**



IV infusion time is about 30 minutes, though actual time in clinic or place of infusion may vary.



Opdualag is usually given every 4 weeks. Your healthcare provider will decide how many treatments you will receive and do blood tests to monitor your health and check for side effects.



Call your healthcare team as soon as possible to reschedule if you miss any of your appointments.



Talk to your healthcare team for more information about this medication.





















### Tips for making the most of your treatment while on Opdualag



Good communication will help you and your healthcare team work together to manage your treatment plan.

- · If there's something you don't understand, ask your doctor to explain until it's clear
- Keep a journal to write down how you are feeling and bring it to your doctor visits
- · Make the most of monthly check-ins with your healthcare team by getting answers to any questions you have



#### You're not alone—create a support team. Your team can be:

- Family and friends who provide emotional support and help with day-to-day tasks
- · Your healthcare team, which is your most important source of information and support
- · Advocacy and support groups for sharing experiences with others and finding resources



Ask your healthcare team for tips on everyday activities such as diet and physical activity.

- A nutritious diet is always important, but especially when you're getting treated
- · Try staying active to maintain your overall well-being

Visit www.Opdualag.com for more information.

Please see <u>Important Facts</u> for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.













### **Connect with others**

Whether you are a patient or caregiver, here are some support groups you can reach out to during your treatment journey.\*



#### AIM at Melanoma

#### aimatmelanoma.org

This organization is globally engaged and locally invested in advancing the battle against melanoma through innovative research, legislative reform, education, and patient and caregiver support.



#### **American Cancer Society**

#### cancer.org

The American Cancer Society's mission is to save lives, celebrate lives, and lead the fight for a world without cancer.



#### CancerCare

#### cancercare.org

The mission of CancerCare is to provide free, professional support services to anyone affected by cancer.



#### **Cancer Research Institute**

#### cancerresearch.org

Cancer Research Institute (CRI) is dedicated to pursuing research in and advancing awareness of immunotherapy for cancer.



#### **Cancer Support Community**

#### cancersupportcommunity.org

This group is an international nonprofit dedicated to providing support, education, and hope to people affected by cancer and their loved ones.



#### Melanoma Research Alliance

curemelanoma.org













**FACTS** 















Research Alliance

(nivolumab and relatlimab-rmbw) Injection for intravenous use | 480 mg/160 mg

#### Melanoma Research Alliance

#### curemelanoma.org

The mission of the MRA is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanomas.



#### Melanoma Research Foundation

#### melanoma.org

The MRF supports medical research for finding effective treatments and eventually a cure for melanoma; educates patients, physicians and the public about the prevention, diagnosis and treatment of melanoma; and acts as an advocate for the melanoma community to raise awareness of this disease and the need for a cure.

\*Bristol Myers Squibb does not endorse these organizations. The information and links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.



Please see Important Facts for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.

























### **Tips for caregivers**

There's no one-size-fits-all plan. Talk with your loved one and healthcare team to create a plan that works for you. And of course, be flexible and adjust along the way.

# You can play an important role, both early on and throughout treatment:

- Help your loved one learn more about treatment
- Go with your loved one to appointments to take notes and ask questions
- Help your loved one become aware of and monitor potential side effects of treatment, with the guidance of your healthcare team
- Keep a calendar with your loved one to keep track of appointments

# Don't forget, as a caregiver, it's important to take care of yourself, too. Here are some ideas:

- Keep up with your own medical needs, including checkups, medications, and other medical necessities
- Make sure you get enough sleep and maintain a healthy diet
- Do exercises you enjoy under the advice of your doctor
- Make time for yourself. Stretch, read, watch television, or talk on the phone—whatever helps you to unwind

Sign up now for Opdualag with You

Please see <u>Important Facts</u> for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.













### **Financial resources**

Patient Access, Reimbursement, and **Co-Pay Support** 

Available through Bristol Myers Squibb Access Support®

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer the BMS Access Support program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

For more information, ask your doctor, visit BMS Access Support, or call BMS Access Support at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday.

# Sign up now for Opdualag, with You

(nivolumab and relatlimab-rmbw) Injection for intravenous use | 480 mg/160 mg

Opdualag with You means just that: we're here to help you better understand Opdualag. This program, designed for people who are prescribed Opdualag and their loved ones, includes the following resources.

#### Sign up and you'll receive:



#### **Helpful Information**

Get useful tips, tools, and educational materials that can help you or your loved one learn more about Opdualag and may help support your care.



#### **Support and Advocacy Groups**

We can direct you to organizations that may be helpful for the challenges you may face.



#### Signing up takes less than 5 minutes.

Just call 1-855-OPDUALAG 8 AM to 8 PM ET, Monday to Friday, or visit www.OpdualagwithYou.com





Call us toll-free at 1-855-436-5866

























ABOUT OPDUALAG WHY OPDUALAG STARTING ON OPDUALAG

IMPORTANT FACTS

EDUCATION & SUPPORT

### **Financial resources**

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Please see **Important Facts** for Opdualag. Please see links below for full Prescribing Information and Medication Guide for Opdualag.

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