

Diagnosed with MCC that has spread or returned?

# YOUR ACTION PLAN STARTS HERE



## A GUIDE FOR PATIENTS AND CAREGIVERS

MCC, Merkel cell carcinoma.

**ZYNYZ**<sup>™</sup>  
retifanlimab-dlwr  
Injection 500 mg

### WHAT IS ZYNYZ<sup>™</sup> (retifanlimab-dlwr)?

ZYNYZ is a prescription medicine used to treat a type of skin cancer called Merkel cell carcinoma in adults. ZYNYZ may be used to treat your Merkel cell carcinoma when it has spread or returned.

It is not known if ZYNYZ is safe and effective in children.

ZYNYZ is approved based on tumor response and duration of response. There are ongoing studies to confirm the clinical benefit of ZYNYZ.

### IMPORTANT SAFETY INFORMATION

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

ZYNYZ is a medicine that may treat a certain type of skin cancer by working with your immune system. ZYNYZ can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please read the Important Safety Information throughout and [click here](#) for Full Prescribing Information, including Medication Guide, for ZYNYZ.



# Taking action against MCC that has spread or returned

When you or your loved one is diagnosed with MCC that has spread or returned (also known as advanced MCC), it can seem overwhelming. You may have questions and concerns about what to do and where to start. This guide can help you put together an action plan. This brochure offers important information about ZYNYZ™ (retifanlimab-dlwr)—and how it can help **you** take action against MCC.



## You can use this space to:

- Write down contact info for your care team
- Record upcoming appointments
- Take notes during healthcare visits
- List questions for your doctor

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## IMPORTANT SAFETY INFORMATION (CONT'D)

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

**Lung problems:** cough, shortness of breath, chest pain

**Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdomen) pain or tenderness

**Liver problems:** 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

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# ZYNYZ—an important part of your plan

ZYNYZ is a prescription medicine used to treat a type of skin cancer called *Merkel cell carcinoma* in adults. ZYNYZ may be used to treat MCC when it has spread or returned. ZYNYZ is not chemotherapy. ZYNYZ is an immunotherapy called a *PD-1 inhibitor*. It may work with your immune system to help fight cancer cells.

## Understanding MCC and treatment with ZYNYZ

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## IMPORTANT SAFETY INFORMATION (CONT'D)

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

**Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

**Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, loss of appetite



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# What is MCC?

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MCC is a rare disease in which cancer cells form in the skin. MCC usually appears as a single red or purple painless lump on sun-exposed skin (such as the head, neck, or arms).

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Sun exposure or a weakened immune system (from certain diseases or medical treatments) can increase the risk of MCC. Other risk factors include being older than 50 years of age, male, or White.

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MCC tends to grow quickly. It is diagnosed with tests and procedures that examine the skin, including skin biopsies.

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CT and PET scans, lymph node biopsies, and lab tests help determine if MCC has spread from where it began to other parts of the body. When this happens, it is called *metastatic MCC*.

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MCC can also come back after it has been treated. This is called *recurrent MCC*.



CT, computed tomography; PET, positron emission tomography.

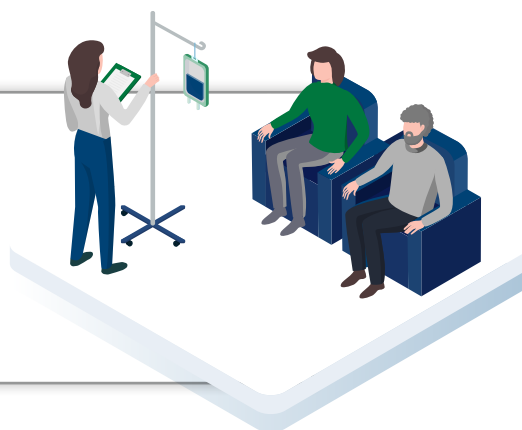
# MCC treatment steps

Treatment of MCC depends on the stage of the disease as well as other factors, such as the location of the tumor. After an initial biopsy to confirm the MCC diagnosis, you and your healthcare team will decide what to do next.



If MCC hasn't spread, you may have surgery to remove the lesion. This may be followed by radiation therapy and close monitoring for recurrent disease.

Your doctor may prescribe an immunotherapy if MCC is diagnosed at a later stage and has spread or has returned after initial treatment. An *immunotherapy* is a type of treatment that helps the body's own immune system fight the disease.



# How does ZYNYZ™ (retifanlimab-dlwr) work?

ZYNYZ is not chemotherapy. It is an immunotherapy called a *PD-1 inhibitor*. It may work with your immune system to help fight cancer cells.

ZYNYZ is **FDA approved** to treat MCC in adults when it has spread or returned. ZYNYZ is approved based on tumor response and duration of response. There are ongoing studies to confirm the clinical benefit of ZYNYZ.

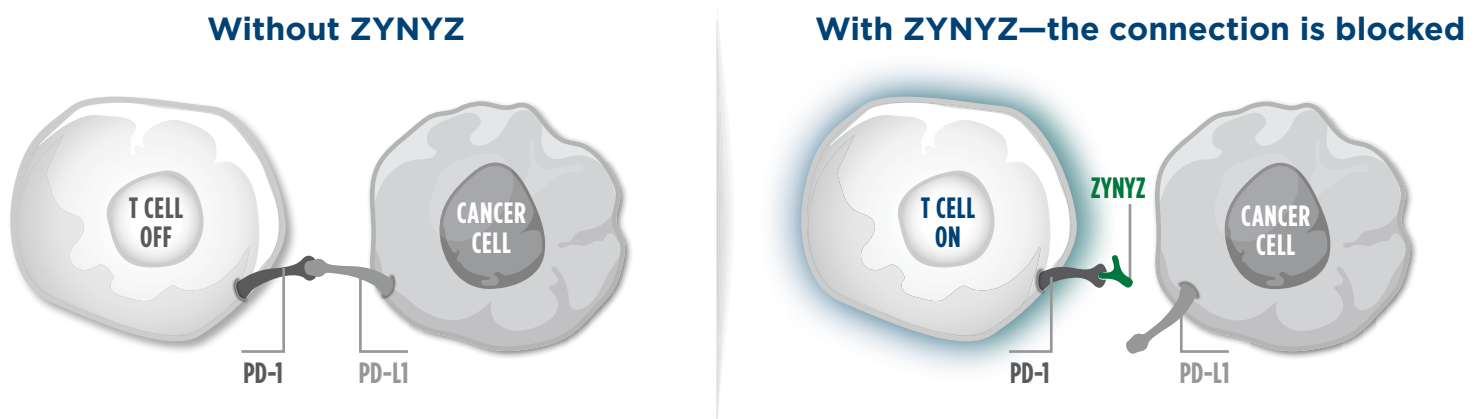
## HOW PD-1 INHIBITORS WORK

Throughout your body, you have immune cells called *T cells*. T cells find and attack threats, like cancer, by using something called the *PD-1 pathway*.

The pathway includes two proteins called:

- *PD-1*, found on the surface of immune cells
- *PD-L1*, found on cancer cells

When PD-1 and PD-L1 join together, they allow cancer cells to hide from T cells. This keeps them from being destroyed by the immune system.



PD-1, programmed death receptor-1; PD-L1, programmed death-ligand 1.

PD-1 inhibitors, like ZYNYZ, block the PD-1 pathway, preventing cancer cells from hiding. This helps the body's immune cells find and destroy them.

## IMPORTANT SAFETY INFORMATION (CONT'D)

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

**Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in your mouth or nose, throat, or genital area; fever or flu-like symptoms; swollen lymph nodes

Please read the Important Safety Information throughout and [click here](#) for Full Prescribing Information, including Medication Guide, for ZYNYZ.

# Take action against MCC with ZYNYZ™ (retifanlimab-dlwr)

ZYNYZ was evaluated in a clinical study in people with MCC that had spread or returned (advanced MCC). The initial assessment that led to the approval of ZYNYZ included 65 people with advanced MCC. Some people in the study had prior surgery or radiation therapy for their MCC. None of the 65 people in the initial assessment received prior therapies like chemotherapy. People whose immune system function was altered by medicines they were receiving (immunosuppressants) or by an active autoimmune disease were not eligible for the study. Patients who were HIV-positive, had an undetectable viral load, had an appropriate CD4+ count, and were receiving appropriate treatment were eligible.

## The study measured:



The number of people who saw their MCC lesions disappear\* (complete response) or shrink in size by a certain amount (partial response) during treatment with ZYNYZ. This was the primary measurement in the study.



How long their response to treatment with ZYNYZ lasted. This is called the *duration of response*. This was a secondary measurement in the study.

\*Disappearance of all signs of cancer in response to treatment does not always mean the cancer has been cured. HIV, human immunodeficiency virus.

## ZYNYZ was shown to be effective in people with MCC that had spread or returned

**52%** of people (34 of 65) in this study responded to treatment with ZYNYZ

- 18% (12 of 65) had a complete response
- 34% (22 of 65) had a partial response

For people who responded to ZYNYZ, the duration of response ranged from **1.1 months to over 24.9 months**



**76%** of people (26 of 34) who responded to ZYNYZ had a response that lasted 6 months or more



**62%** of people (21 of 34) who responded to ZYNYZ had a response that lasted 12 months or more

## IMPORTANT SAFETY INFORMATION (CONT'D)

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with ZYNYZ. Call or see your doctor right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

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# A plan for receiving ZYNYZ™ (retifanlimab-dlwr)

Your doctor will administer 500 mg of ZYNYZ into a vein through an intravenous (IV) line over 30 minutes. The infusion will be done at a hospital, a doctor's office, or an infusion center.



ZYNYZ is usually given every 4 weeks. Your doctor will decide how many treatments you will need.



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



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



## Preparing for treatment

There are some things you can do to help improve the overall treatment experience:

- Gather a support team of helpers who can drive you to and from appointments or help at home if necessary
- Pack a bag with things to keep you or your loved one occupied and comfortable during the infusion, like books, a tablet or other device, and warm clothing
- Eat well, get enough sleep, and drink plenty of fluids

## IMPORTANT SAFETY INFORMATION (CONT'D)

**Infusion reactions that can sometimes be severe. Signs and symptoms of infusion reactions may include:** chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain

**Rejection of a transplanted organ.** Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

**Complications, including graft-versus-host disease, in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with ZYNYZ. Your doctor will monitor you for these complications.

**Getting medical treatment right away may help keep these problems from becoming more serious.**

Your doctor will check you for these problems during your treatment. Your doctor may treat you with corticosteroid or hormone replacement medicines and may also need to delay or completely stop treatment if you have severe side effects.

Please read the Important Safety Information throughout and [click here](#) for Full Prescribing Information, including Medication Guide, for ZYNYZ.



## IMPORTANT SAFETY INFORMATION (CONT'D)

**Before you receive ZYNYZ, tell your doctor about all of your medical conditions, including if you:**

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. ZYNYZ can harm your unborn baby.

### **Females who are able to become pregnant:**

- Your doctor should do a pregnancy test before you start treatment.
- You should use an effective method of birth control during your treatment and for 4 months after your last dose. Talk to your doctor about birth control methods that you can use during this time.
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment.
- are breastfeeding or plan to breastfeed. It is not known if ZYNYZ passes into your breast milk. Do not breastfeed during treatment and for 4 months after your last dose.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**The most common side effects of ZYNYZ include** tiredness, muscle and bone pain, itching, diarrhea, rash, fever, nausea

These are not all the possible side effects of ZYNYZ. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **General information about the safe and effective use of ZYNYZ**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about ZYNYZ, talk with your doctor. You can ask your doctor for information about ZYNYZ that is written for health professionals.



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## Additional resources\* to help you take action

Finding out that you or a loved one has MCC that has spread or returned can be overwhelming, but you don't have to go on this journey alone. Friends and family can help just by being with you at appointments, whether they're asking questions or keeping track of information. It may also be helpful to find a group of others going through the same journey.

**Cancer.org can provide information on programs and services and locate groups that might work for you. The following resources may also be able to help:**



**\*Incyte Corporation is not affiliated with these organizations but may have provided funding for some of their educational programs.**

### Helpful questions to ask your doctor

To make the most out of visits with your doctor, you may find it helpful to ask some of the following questions:

- What makes ZYNYZ™ (retifanlimab-dlwr) right for me or my loved one?
- How long will treatment last?
- Where will treatment take place?
- What are possible side effects of ZYNYZ?
- Will I or my loved one be able to work or care for family while on treatment?
- How will I know if treatment is working?
- After being on ZYNYZ, will additional treatment be needed?

## IMPORTANT SAFETY INFORMATION

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

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# Access and support: IncyteCARES

## WE'RE HERE TO HELP YOU WITH YOUR ACTION PLAN

IncyteCARES is a dedicated patient assistance program developed by Incyte, the makers of ZYNYZ.

At IncyteCares, our mission is to help patients access prescribed Incyte medications and to offer information and resources that provide extra support during treatment. In addition, our team is available by phone every weekday to provide support to help you on your treatment path.



Visit IncyteCARES:

Go to [www.incyteCARES.com/ZYNYZ](http://www.incyteCARES.com/ZYNYZ) or call us at:  
1-855-452-5234 (Monday through Friday, 8 AM-8 PM ET)

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