

# YOUR KIMMTRAK® (tebentafusp-tebn) ACTION PLAN

(to be filled out by a member of your oncology team)

Patient Name	<b>Date</b>	
Discussion of Typ	oical Side Effects	
Fever	Next steps/Action items:	
Low blood pressure		
Dizziness		
Headache		
Chills_		
Wheezing and trouble breathing		
Nausea		
	_	
Skin rash		
Itch		
Skin peeling		
Bruising or bleeding		
Diarrhea		
Tiredness or weakness	_	
☐ Joint pain		
Swelling (stomach or skin)		
Please share this important information with your caregiver and loved ones so they can help support you during your treatment.		

IMMUNOCORE RESOURCES KIMMTRAK CONNECT®

Support, financial assistance, and care coordination

844-755-2273

www.kimmtrakconnect.com/



# **ARE YOU A CANDIDATE FOR KIMMTRAK®?**

KIMMTRAK® (tebentafusp-tebn)

If you have been diagnosed with uveal melanoma that is unresectable (meaning that it can't be removed by surgery) or metastatic (meaning it has spread), you may be eligible to take Kimmtrak. Kimmtrak is an immunotherapy, a medicine that helps your body's immune system kill tumor cells. Kimmtrak is available for patients who are positive for the human leukocyte antigen (HLA) *HLA-A\*02:01* gene. Your body uses HLA to determine which cells belong in your body and which do not. Nearly half of patients with uveal melanoma are *HLA-A\*02:01* positive and that doesn't change over time. Because Kimmtrak can only be used in patients who test positive for *HLA-A\*02:01*, you will need to be tested to see if you are eligible. Here's how that process works:

- After being diagnosed with uveal melanoma, ask your doctor about a simple blood test for the *HLA-A\*02:01* gene. A biopsy is not needed, the blood test is the accurate way to see if you are *HLA-A\*02:01* positive
- You and your doctor will receive the results of the blood testing in approximately 1-2 weeks
- · After receiving the test results, you should discuss your treatment options with your doctor

# TAKING THE MEDICATION

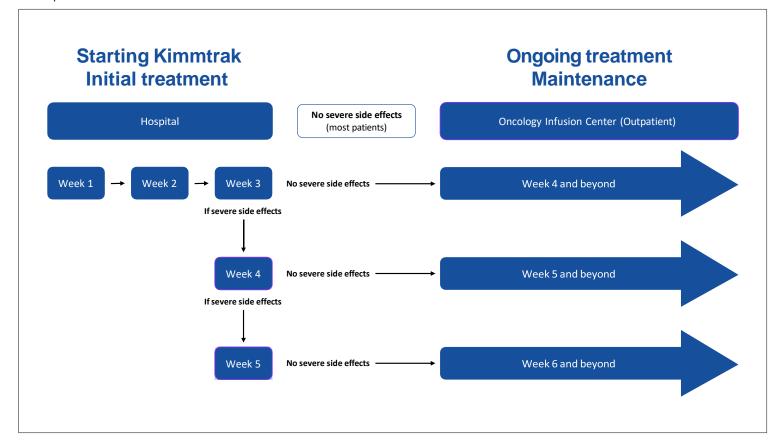
KIMMTRAK® (tebentafusp-tebn)

#### **HOW IT'S GIVEN:**

- Kimmtrak is given through your vein via an intravenous (IV) line. The treatment takes 15-20 minutes
- Treatments are given every 7 days on an ongoing basis
- Initial treatment: The initial doses (at least the first three) are typically given in the hospital, where you will need to stay overnight. You will be monitored closely over a 16-hour period for signs of cytokine release syndrome, which can require specialized supportive care and prompt treatment, as described below
- Ongoing maintenance: As long as you are tolerating your treatment with Kimmtrak, you will be able to receive your treatment at your oncologist's infusion center (outpatient) after three doses. If you are having difficulty with side effects, you may need to get your fourth or fifth dose in the hospital
- Generally, treatment is given on an ongoing basis. Your oncologist will decide if any change in your treatment is needed
- You will need to have blood tests before your first treatment and every three weeks during your treatment with Kimmtrak. Your doctor may also order scans or other imaging tests (eg, magnetic resonance imaging [MRI], computerized tomography [CT] scans) every 2-3 cycles
- It is important to keep appointments with your oncology team to receive your treatment. If you miss an appointment, call as soon as possible to reschedule and to receive instructions about what to do



Graphic. Kimmtrak treatment schedule.



# WHAT TO EXPECT

KIMMTRAK® (tebentafusp-tebn)

#### STARTING KIMMTRAK: IN THE HOSPITAL

- You will start Kimmtrak at a low dose to be sure you are tolerating the treatment. As long as you are tolerating
  Kimmtrak and don't have serious side effects, your dose of Kimmtrak will be increased at the second dose and you'll start
  getting the full dose of Kimmtrak at your third treatment
- A nurse will check on you every few hours. They will take your blood pressure, pulse, and temperature, and check your oxygen levels
- You might develop a fever and rash. You may become itchy, have difficulty sleeping, have a poor appetite, and be very tired. Side effects typically start approximately eight hours after receiving your treatment. Most of these symptoms will resolve by the time you are released from the hospital
- You might still have a rash for another 24 hours after you go home
- Your oncology team will give you medication (oral or IV) or other treatments to manage any side effects. In some cases, you will receive medication before your treatment to prevent or reduce the severity of any side effects
- You and your caregiver should tell your oncology team about any side effects
- You should continue to take your regular medications while you are in the hospital unless your doctor tells you otherwise



(What to Expect continued)

# ONGOING MAINTENANCE TREATMENT WITH KIMMTRAK: IN YOUR ONCOLOGIST'S INFUSION CENTER (OUTPATIENT)

- · You will receive your treatments weekly on an ongoing basis
- Following your treatment with Kimmtrak, you'll be watched for approximately 30 minutes by your infusion specialist to be sure you are not having any serious side effects
- You may feel tired or fatigued after each treatment for up to 24 hours and may need extra rest. Until you know how you
  may feel after each treatment, you may not want to make plans that day
- You may have other side effects, but they are usually milder than what you experienced in the hospital and become less frequent over time. In most patients, side effects go away after 2-3 months

#### **COMMON SIDE EFFECTS WITH KIMMTRAK:**

Side effects are most likely to occur with the first three doses while you are in the hospital. Over time, side effects occur less often and tend to be milder. Less than 5% of patients stop treatment because of side effects with Kimmtrak.

Even minor side effects could be serious, and you should report them all to your oncology team. The most common side effects of taking Kimmtrak are:

- Cytokine release syndrome (symptoms may include fever, low blood pressure, trouble breathing, confusion —see the following page for more information):
- Fever\*
- Rash\*
- Itching
- Tiredness\*
- Nausea\*
- Chills\*
- Swelling
- Low blood pressure\* (symptoms may include dizziness or light-headedness)
- Dry skin
- · Headache\*
- Vomiting\*
- Abnormal liver blood tests/liver problems (symptoms may include yellowing of the skin and whites of eyes, severe stomach pain confusion/fogginess)

 ${}^*\mathit{Symptoms}$  of cytokine release syndrome

# Tips for caregivers:

# WHEN YOUR LOVED ONE IS GETTING TREATMENT IN THE HOSPITAL:

Even though the nurse will be checking in every few hours, you should be on the lookout for any sudden changes. Alert the nurse immediately if your loved one:

- · Is having any trouble breathing, talking, or wheezing
- · Seems confused or foggy
- · Has severe nausea or vomiting
- · Faints, falls, is very dizzy
- Has any sudden change in rash, intense itching or the rash is quickly getting worse

#### **AVOID PREGNANCY:**

You will need a pregnancy test before you start treatment with Kimmtrak. Use birth control during therapy and for 1 week if you stop treatment if you are of childbearing age. Tell your oncologist's office right away if you become pregnant or think you are pregnant while on Kimmtrak, as it can cause harm to an unborn baby. You should not breastfeed during treatment with Kimmtrak and for at least 1 week after treatment has stopped because it is not known if it passes it into your breastmilk.

#### IMPORTANT SIDE EFFECTS

Your oncology team may discuss some side effects of Kimmtrak that can lead to serious problems if they aren't taken care of right away. These sections give information about possible symptoms, what you should tell your oncology team, when you should get immediate medical help, and any steps you can take to help ease the symptoms.



# **CYTOKINE RELEASE SYNDROME**

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Report immediately to your oncology team

## What is cytokine release syndrome?

Cytokine release syndrome is a reaction of the immune system that can occur after treatment with some types of immunotherapies. It is caused by a large, rapid release of certain substances, called cytokines, into the blood from the immune cells (T cells) when your immune system is activated by the immunotherapy. Cytokines have many different actions in the body and can cause a wide range of side effects. Cytokine release syndrome can sometimes be severe or life-threatening, but it can be treated with medication and managed by your oncology team.

Cytokine release syndrome is most common with the first three doses of Kimmtrak while you are in the hospital. It usually occurs on the day of the treatment, and most of the symptoms resolve by the time you leave the hospital. In most cases, it is not severe, especially when it is caught early and treated.

## What are the symptoms?

- Fever
- Tiredness or weakness
- Vomiting

- Chills
- Nausea
- · Low blood pressure
- Dizziness and lightheadedness
- Headache

- Wheezing
- Trouble breathing
- Confusion

#### WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

## When you are in the hospital

- When you first noticed the symptoms and if anything has changed since your nurse or oncology team member last checked in on you
- · Any sudden change in your symptoms or if your symptoms become more severe
- · If you have had any breathing or skin problems in the past

# Red flag(s):

- · If you are unable to speak, have difficulty breathing, or are wheezing
- · If you are confused, foggy, or have trouble thinking
- If you have severe nausea and vomiting and can't eat or drink
- If you have severe dizziness, light-headedness or if you faint or fall

## Taking care of yourself:

- Tell your oncology team about all medications you are taking including any over the counter drugs, vitamins, herbal medicines, or other natural treatments. Don't take anything new without talking to your doctor
- · Take all your regular medicines, unless your doctor tells you otherwise
- Get plenty of fluids and don't let yourself get dehydrated
- · Make sure to eat
- Be careful standing by yourself in the hospital. You may not want to go to the bathroom alone if you feel dizzy or unsteady on your feet. Ask your caregiver or nurse for assistance
- · Stop smoking before going into hospital and limit your alcohol intake



# **SKIN CHANGES**

KIMMTRAK® (tebentafusp-tebn)

Report immediately to your oncology team

## What are the symptoms?

- · Skin rash with or without itching
- Dry skin
- Skin redness

- · Change in skin color (lighter)
- · Skin swelling or peeling
- · Change in hair color

A skin rash is a common side effect and actually is a sign that the drug is working. Rashes tend to be most severe with the first three doses of Kimmtrak and become milder and less frequent over time.

#### WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

## When you are in the hospital

- When you first noticed the rash and if anything has changed since your nurse or oncology team member last checked in on you
- · If you have had any skin problems in the past



## Red flag(s):

- · Any sudden change in your rash or if your rash is quickly getting worse
- If your skin is peeling and/or you have intense itching especially if it is interfering with your ability to sleep

## When you are at home

- · When you first noticed the rash
- What the rash looks like (eg, flat, bumpy, red, acne-like, hives)
- · Where the rash is and how much of the body it is covering
- · If the skin change is making it difficult for you to get dressed, perform daily activities, or sleep
- · If you have had any skin problems in the past
- If you have started any new medications, supplements, or vitamins recently
- · If you have been using a new soap or have been around new chemicals or animals recently
- What you have tried at home to manage the symptoms



## Red flag(s):

- · If you have a rash that covers a large part of your body, is not going away, or is quickly getting worse
- · If your skin is peeling and/or you have intense itching that is interfering with your ability to function and/or sleep

# Taking care of your skin:

- Avoid soap. Instead, use gentle, non-soap cleansers such as Cetaphil<sup>®</sup>
- · Avoid hot showers or baths (short, lukewarm showers are OK)
- · Apply a cool cloth to the area
- · Apply a cooling cream with menthol or camphor to the area (refrigerate the cream first for even greater relief)
- · Keep your fingernails short to protect your skin from damage if you scratch
- Apply a moisturizer that contains the ingredients urea or glycerin daily such as Aquafor® or CeraVe®
- · Don't use lotions that have perfumes or dyes
- · Protect your skin from the sun by wearing sunscreen, a hat, and UV-protective clothing and sunglasses
- · Don't forget your hands and face
- Your oncology team may tell you to take an antihistamine by mouth or apply a corticosteroid cream to reduce the itching. You
  also may be prescribed an oral corticosteroid if your itching is more intense



# OTHER SYMPTOMS OR ABNORMAL BLOOD TESTS TO LOOK OUT FOR

Below are other symptoms that you can have when you take Kimmtrak<sup>®</sup> (tebentafusp-tebn). We are very concerned about symptoms we have marked with a check mark. Please call the office if you develop any of these symptoms and consider going directly to the Emergency Room if you have any of the red-flag symptoms.

<b>/</b>	Symptoms or blood test problems	Red flags (Signs that something serious is going on that needs immediate attention)
	Liver problems (bruising or bleeding more easily, changes in the color of your stool or urine, stomach pain or swelling/bloating, yellowing of your skin or whites of your eyes, confusion, drowsiness, excessive sweating)	<ul> <li>If you have severe pain and/or swelling in your stomach, particularly if the pain is also on the upper right side of the stomach</li> <li>Your skin or the whites of your eyes have turned yellow</li> <li>You feel confused or foggy or very drowsy all day</li> </ul>
	Diarrhea	If you have sudden, severe pain or tenderness in the stomach, especially if you also have a fever
	Fatigue (feeling weak, tired or have low energy)	You're very drowsy all day or if you faint
	Joint pain	<ul> <li>Severe, unexplained joint pain that lasts for more than several days.</li> <li>You also have a fever over 104.0 °F and you don't have a cold or flu</li> </ul>
	Swelling (stomach or skin)	If you also have a severe rash or intense itching     If you have severe stomach pain



# PATIENT RESOURCES

#### ADDITIONAL INFORMATION RESOURCES

**AIM at Melanoma Foundation** (Ask an Expert program, patient symposia, drug resources, etc) https://www.aimatmelanoma.org/

American Cancer Society: Immunotherapy and Targeted Drugs for Eye Cancer https://www.cancer.org/cancer/types/eye-cancer/treating/targeted-therapy.html

#### **FINANCIAL ASSISTANCE**

#### KIMMTRAK CONNECT®

Financial assistance and personalized care coordination for patients taking Kimmtrak. <a href="https://www.kimmtrakconnect.com/">www.kimmtrakconnect.com/</a>
844-755-2273

#### **Cancer Financial Aid Coalition**

Facilitates communication, educates and advocates for patients. www.cancerfac.org

#### **Centers for Medicare and Medicaid Services (CMS)**

Apply to determine if you are eligible for government assistance. <a href="https://www.cms.gov">www.cms.gov</a> or <a href="https://www.medicare.gov">www.medicare.gov</a> 800-633-4227

#### **Lazarex Foundation**

Provides assistance with travel costs for clinical trial participation. Ask your social work counselor for a referral if you have been consented to a clinical trial for melanoma. www.lazarex.org

#### **Needymeds**

Database to search for free or low-cost medications, help with medical transportation and other resources. www.needymeds.org

#### **Patient Advocate Foundation**

Provides assistance with mediation, financial stability, and other assistance. Funds subject to availability. Patient must meet their eligibility for financial assistance.

www.patientadvocate.org

800-532-5274

#### The Sam Fund for Young Adult Survivors of Cancer

Assists cancer survivors ages 21-39 with their transition into post-treatment life. This program distributes grants and scholarships in an effort to enable survivors to pursue goals.

www.thesamfund.org info@thesamfund.org



#### PRESCRIPTION ASSISTANCE

#### **CancerCare Co-Payment Assistance Foundation**

Helps with the cost of medication. Availability of funds for patients with Stage IV melanoma subject to availability. www.cancercarecopay.org

1-866-552-6729

#### **Medicine Assistance Tool**

Database to search for patient assistance resources offered by pharmaceutical companies. www.medicineassistancetool.org/

#### **Patient Advocate Foundation Co-Pay Relief**

Provides direct financial support to patients who medically qualify. Availability of funds for patients with Stage IV melanoma subject to availability.

www.copays.org

1-866-512-3861

#### **Good Days**

Formerly known as the Chronic Disease Fund. Provides assistance with insurance co-pays, and prescription medications. Availability of funds for patients with Stage IV melanoma subject to availability. www.mygooddays.org

#### **HealthWell Foundation**

For patients who cannot afford insurance premiums, co-payments, co-insurance, or other out-of-pocket health care costs. Availability of funds for patients with Stage IV melanoma subject to availability. Patient must also meet eligibility for financial assistance.

www.healthwellfoundation.org or grants@healthwellfoundation.org

1-800-675-8416

#### The Assistance Fund, Inc

Provides prescription copay and financial assistance, including health insurance premiums. Availability of funds for patients with Stage IV melanoma subject to availability.

www.theassistancefund.org

1-855-845-3663

#### **PAN Foundation**

Provides financial assistance to cover out-of-pocket treatment costs. Availability of funds for patients with Stage IV melanoma subject to availability.

www.panfoundation.org

1-866-316-PANF (7263)

#### **Patient Assistance Program**

Comprehensive database of patient assistance programs offering free medications.

www.rxassist.org

info@rxassist.org



### HOUSING

#### American Cancer Society - Hope Lodge

Provides free housing during treatment appointments. Requires a referral from your social worker. www.cancer.org/

1-800-227-6333

### TRANSPORTATION (AIR AND GROUND)

#### Medicaid

Ground transportation only. Sets up rides and provides mileage reimbursement for Medicaid patients only.

1-877-633-8747

#### **Mercy Medical Angels**

Provides free medical transportation (flights, gas cards, bus and train tickets) for patients with financial needs who need to travel more than 50 miles. Patients must meet their eligibility for financial assistance. www.mercymedical.org/

#### **Pilots for Patients**

Provides free flights to people in need of medical treatment. Patient must be medically stable to fly and be ambulatory. Ask your social worker about a referral.

www.pilotsforpatients.org

318-322-5112