KIMMTRAK®
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

For adults with metastatic uveal melanoma who are HLA-A*02:01 positive

# KIMMTRAK provides the promising potential to live longer

**KIMMTRAK is the only FDA-approved immunotherapy for metastatic uveal melanoma.**

Individual results may vary.

## Usage

KIMMTRAK is a prescription medicine used to treat HLA-A*02:01-positive adults with uveal melanoma that cannot be removed by surgery or has spread.

## Important Safety Information

**What is the most important information I should know about KIMMTRAK?**

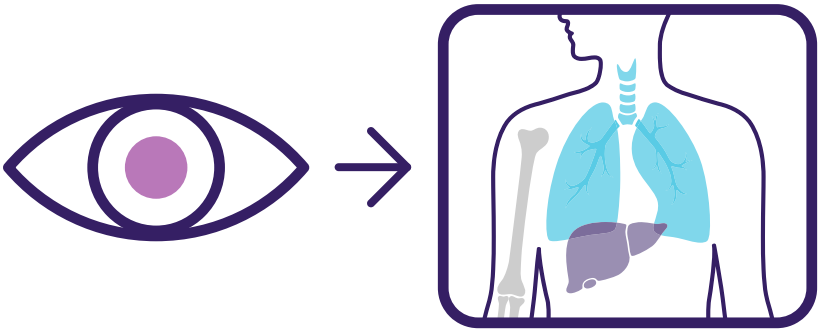
**KIMMTRAK can cause serious side effects that can be severe or life threatening and usually happen within the first three infusions, including:**

- **Cytokine Release Syndrome (CRS). Symptoms of CRS may include:** fever, tiredness or weakness, vomiting, chills, nausea, low blood pressure, dizziness and light-headedness, headache, wheezing and trouble breathing, rash.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

# What is metastatic uveal melanoma (mUM)?

Uveal melanoma (UM) is a rare type of cancer that starts in a part of the eye called the uvea. If uveal melanoma spreads (metastasizes) beyond the eye, it is referred to as metastatic uveal melanoma (mUM). Approximately half of the people who get uveal melanoma will at some point develop metastatic disease and the cancer will spread to other parts of the body, most commonly the liver.



**Uveal melanoma cancer cells spread by traveling through the blood and forming a tumor in a different part of the body.**

## Treatment should be tailored for the disease

Although it's a melanoma, mUM is biologically different from metastatic skin melanoma. Some therapies, including immunotherapies, have been shown to improve outcomes in patients with metastatic skin melanoma, but not in patients with mUM.

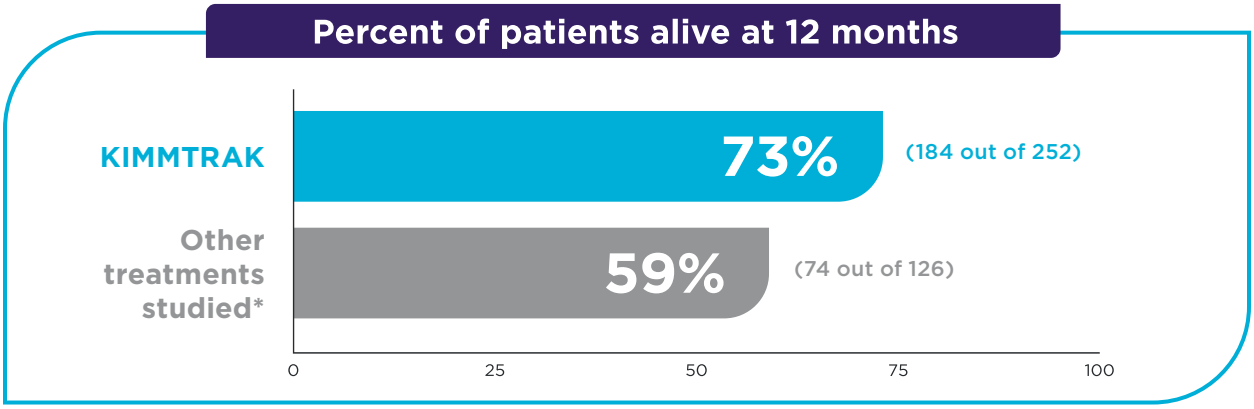
There are many treatments that have been FDA approved to treat metastatic skin melanoma, but only one immunotherapy, KIMMTRAK, has been FDA approved for adult patients with mUM who are HLA-A*02:01 positive. KIMMTRAK has not been FDA approved to treat skin melanoma.

### Important Safety Information (continued)

Tell your healthcare provider right away if you experience any CRS symptoms. Your healthcare provider will check for these problems during treatment with KIMMTRAK. Your healthcare provider may temporarily stop or completely stop your treatment with KIMMTRAK if you have severe side effects.

# Why KIMMTRAK?

## KIMMTRAK is the only FDA-approved immunotherapy for metastatic uveal melanoma (mUM)





Average time that someone who received KIMMTRAK lived was **21.7 months compared to 16.0 months** with other treatments studied.*

* Other treatments studied in the trial included immunotherapies (pembrolizumab or ipilimumab) or chemotherapy (dacarbazine).

Treatment-related **side effects were generally predictable** (expected to occur) and were managed with certain medications.

### Important Safety Information (continued)

- **Skin reactions.** KIMMTRAK may cause skin reactions that require treatment. Tell your healthcare provider if you get symptoms of skin reactions—such as rash, itching, or skin swelling—that are severe and do not go away.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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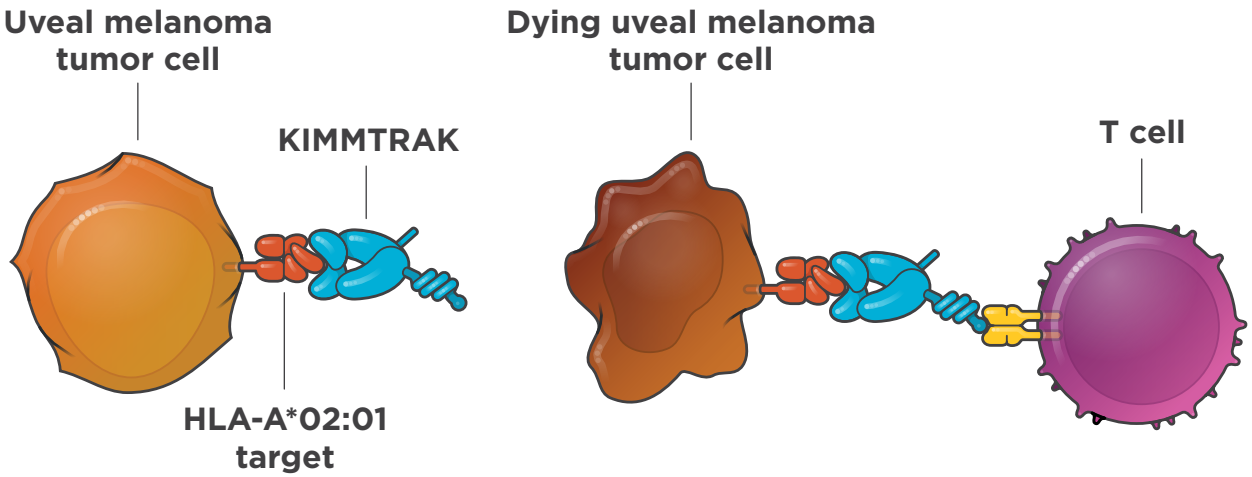
# How does KIMMTRAK work?

## Harnessing the power of your immune system

**Your immune system protects your body from foreign threats, like viruses and cancer, by activating your T cells that can fight and kill these threats. Sometimes, T cells need help knowing which threats to attack.**




**KIMMTRAK** is only for adults with metastatic uveal melanoma who are HLA-A*02:01 positive. **KIMMTRAK** attaches to the HLA-A*02:01 target found on uveal melanoma tumor cells in those who are HLA-A*02:01 positive.

This helps your body's T cells recognize, attack, and kill difficult-to-find uveal melanoma tumor cells. Normal skin cells could also be affected.

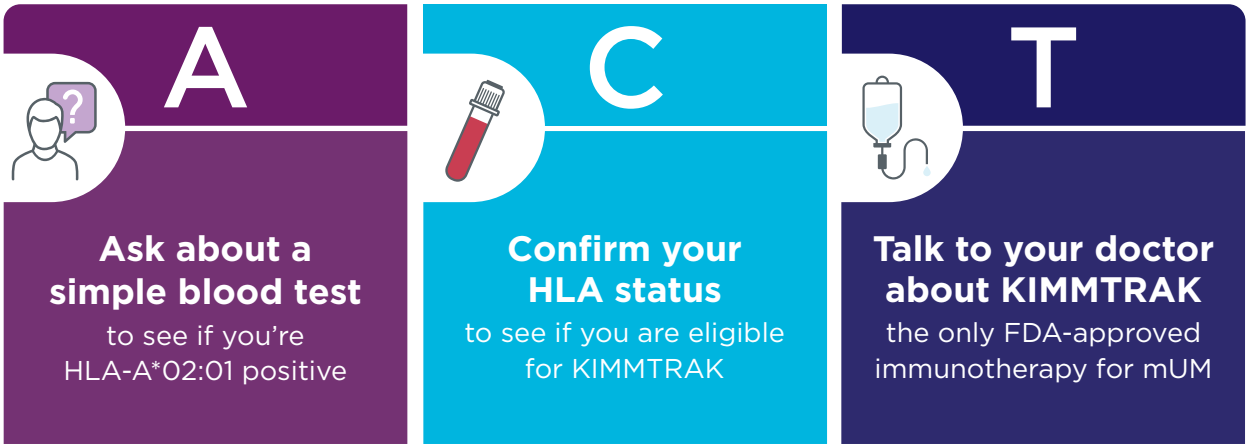
### Important Safety Information (continued)

- **Abnormal liver blood tests**. Your healthcare provider will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK.

# What is HLA-A*02:01, and why is it important in metastatic uveal melanoma (mUM)?

- Human leukocyte antigen (HLA) is a set of genes that may help the immune system find and destroy cancer.
- Nearly half of adults are HLA-A*02:01 positive, and your status doesn't change over time.
- If you're HLA-A*02:01 positive, you may be eligible for KIMMTRAK, the only FDA-approved immunotherapy specifically for adults who have mUM and are HLA-A*02:01 positive.

**If you've been diagnosed with metastatic uveal melanoma (mUM), it's time to:**




**ACT NOW. Request the test.**

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## Find out if you are HLA-A*02:01 positive.

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Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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# KIMMTRAK clinical trial results (primary)

## KIMMTRAK was studied in a large phase 3 clinical trial in adults with metastatic uveal melanoma (mUM) who were HLA-A*02:01 positive and had not received previous treatment for their cancer

**378 adults with mUM who were HLA-A*02:01 positive participated.**

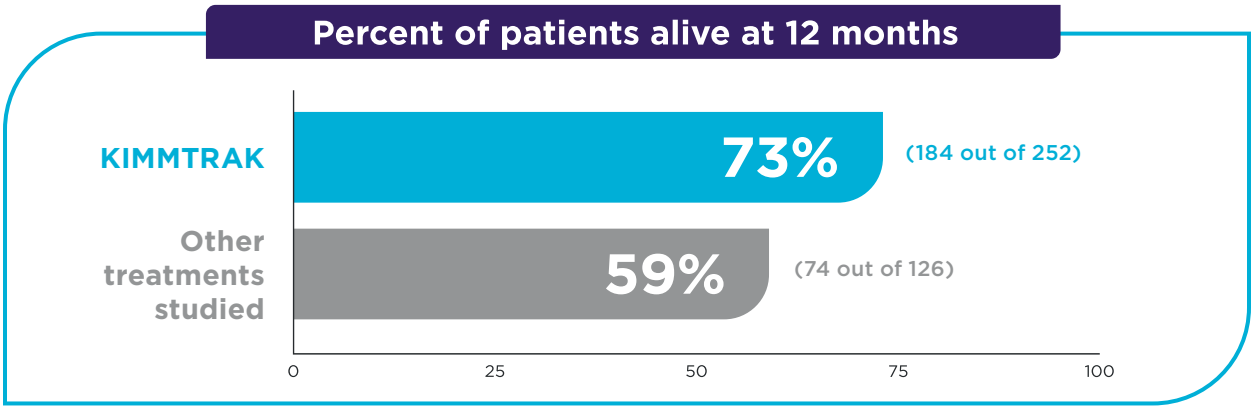
**21.7 months**

### Primary analysis:

- The average time that someone who received KIMMTRAK lived was 21.7 months compared to 16.0 months with other treatments studied, including:
  - Immunotherapies (pembrolizumab or ipilimumab)
  - Chemotherapy (dacarbazine)

On average, patients had 14.1 months of follow-up.

**These results were statistically significant.**




### Important Safety Information (continued)

Tell your healthcare provider if you get symptoms of liver problems such as right-sided abdominal pain or yellowing of the skin or eyes.

# KIMMTRAK clinical trial results (3-YEAR follow-up)

## After the primary analysis, patients continued to follow the clinical trial procedures

### In a follow-up analysis of the clinical trial:

- The average time that someone who received KIMMTRAK lived was 21.6 months compared to 16.9 months with other treatments studied, including:
  - Immunotherapies (pembrolizumab or ipilimumab)
  - Chemotherapy (dacarbazine)

**27.4% of KIMMTRAK patients were alive at 3 years**

(69 out of 252)

**Compared to 17.8% (22 out of 126) of patients who received other treatments studied**

All patients included in these results had at least 36 months of follow-up, and on average, they had 43.3 months of follow-up.

**These data were not tested for statistical significance. KIMMTRAK may not work for everyone. Individual results may vary.**

### Important Safety Information (continued)

**The most common side effects of KIMMTRAK include:** cytokine release syndrome (CRS), rash, fever, itching, tiredness, nausea, chills, stomach pain, swelling, low blood pressure (symptoms may include dizziness or light-headedness), dry skin, headache, vomiting, and abnormal liver blood tests.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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# What side effects have been seen with KIMMTRAK?

## The most common side effects of KIMMTRAK include:

- Cytokine release syndrome (CRS)
- Rash
- Fever
- Itching
- Tiredness
- Nausea
- Chills
- Stomach pain
- Swelling
- Low blood pressure (symptoms may include dizziness or light-headedness)
- Dry skin
- Headache
- Vomiting
- Abnormal liver blood tests

## Side effects related to KIMMTRAK are generally predictable (expected to occur) and can be managed with certain medications

- In the clinical trial, side effects usually happened during the first few doses.
- In the clinical trial primary analysis, 3.3% (8 out of 245) of patients stopped taking KIMMTRAK due to treatment-related side effects.
- In the 3-YEAR follow-up analysis, no new safety issues were observed and side effects were similar to those previously seen in the primary analysis.

**Pay attention to how you are feeling, and talk to your doctor if you have any questions.**

# What side effects have been seen with KIMMTRAK? (continued)

## Possible side effects

Some side effects may occur as a reaction from your immune system responding to treatment. Knowing what side effects to expect and when they are most likely to occur can help you prepare.

## Cytokine release syndrome (a serious reaction of the immune system that can be managed with certain prescription medications)

- 89% of patients experienced some symptoms of CRS. 84% of the time, CRS started the day of the infusion.
- 1.2% discontinued their treatment as a result.
- Symptoms of CRS may include fever, tiredness or weakness, vomiting, chills, nausea, low blood pressure, dizziness and light-headedness, headache, wheezing and trouble breathing, and rash.
- Fever is usually the first sign of CRS, so let your healthcare team know if you are feeling feverish. They will want to track your symptoms closely so they can manage them.
- In the clinical trial, CRS usually decreased and was less severe after the first few doses.

# What side effects have been seen with KIMMTRAK? (continued)

## Rash

- Rash occurred in 83% of patients.
  - None discontinued their treatment due to rash.
- A red rash can appear on all or part of the body, and it may peel or feel itchy and painful. It may appear similar to a sunburn but can look and feel differently for each individual.
- In the clinical trial, most rashes got better or went away over time.

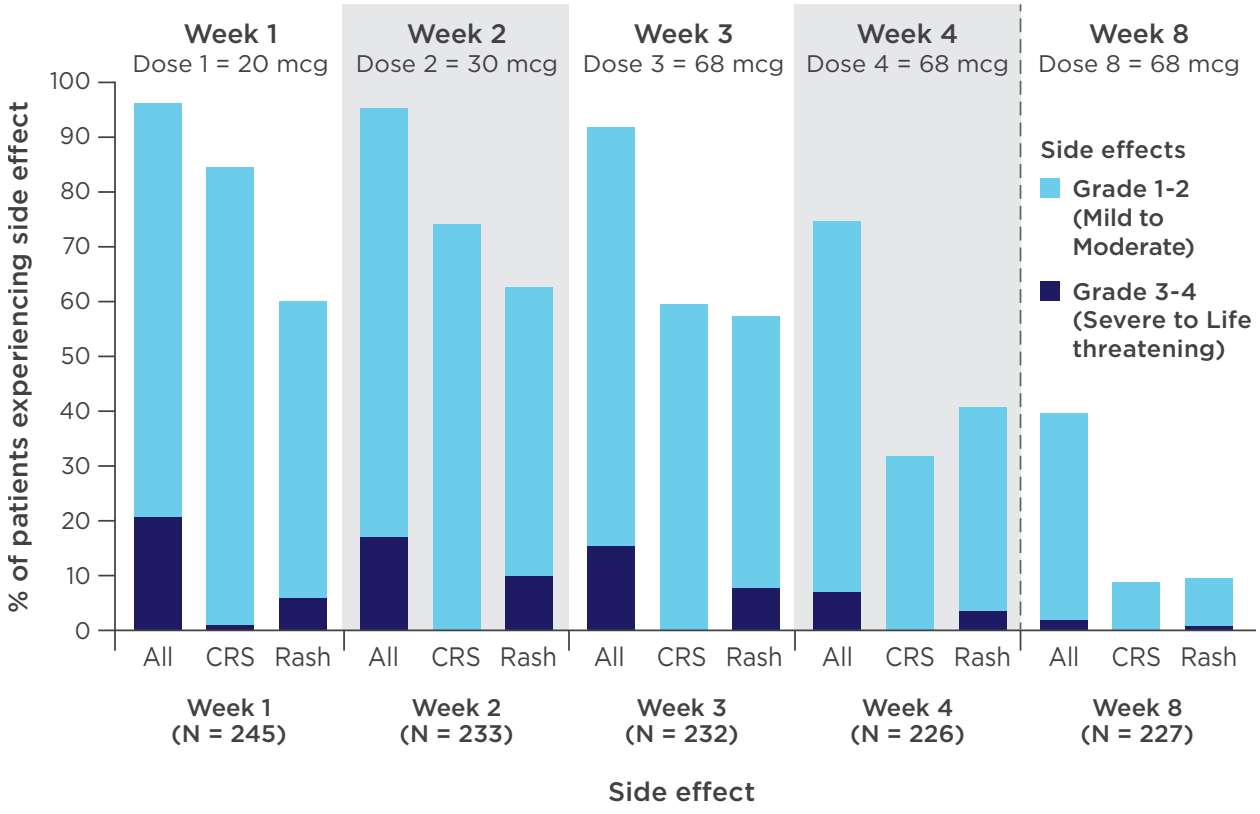
## Abnormal liver blood tests

- 65% of patients had elevated liver enzymes.
  - 0.4% discontinued their treatment as a result.
- Symptoms may include right-sided abdominal pain or yellowing of the skin or eyes.
- Your healthcare provider will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK.

**NOTE: These are not all the possible side effects of KIMMTRAK. Call your doctor for medical advice about side effects.**

# What side effects have been seen with KIMMTRAK? (continued)

## How often certain side effects* happened each week during treatment with KIMMTRAK




* Treatment-related side effects.

CRS was identified by using the American Society for Transplant and Cellular Therapy (ASTCT) criteria.

Rash includes a variety of skin-related side effects.

This chart was published in the *New England Journal of Medicine* in 2021. 

N = Number of patients taking KIMMTRAK.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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# Once-weekly KIMMTRAK

## KIMMTRAK is given once weekly in the form of an IV infusion over 15-20 minutes

**Initiation**


Your healthcare team will watch you during your infusion and for **at least 16 hours** after you are given each of the first 3 doses.

**Maintenance**


If you tolerated your first 3 doses of KIMMTRAK well and you didn't have significant side effects, you will be watched during your infusion and for **a minimum of 30 minutes** after your next doses.

**NOTE: In addition to the potential side effects previously mentioned, you may feel tired or fatigued after each infusion as your immune system becomes activated. Until you know how you may feel after each infusion, you may not want to make plans. Let those who count on you know that you may need extra rest.**

# Ask your doctor about KIMMTRAK for metastatic uveal melanoma

Consider discussing the following questions with your doctor to help determine if KIMMTRAK may be the right treatment for you:

## Thinking about KIMMTRAK?

- Am I a candidate for KIMMTRAK?
- Could KIMMTRAK help me live longer?
- What are the possible side effects and safety considerations of KIMMTRAK?
- How soon can I start KIMMTRAK?

## Where will I go to receive KIMMTRAK?

- Which healthcare professionals will oversee my treatment?
- Who do I contact with questions and/or concerns?
- What can I expect at the treatment center?

**You and your doctor will work together to determine if treatment with KIMMTRAK will help you meet your treatment goals.**

## Important Safety Information (continued)

- **Cytokine Release Syndrome (CRS). Symptoms of CRS may include:** fever, tiredness or weakness, vomiting , chills, nausea, low blood pressure, dizziness and light-headedness, headache, wheezing and trouble breathing, rash.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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# KIMMTRAK CONNECT® is here for you

You are not in this alone. If you and your doctor have decided KIMMTRAK is right for you, the KIMMTRAK CONNECT team is here. They can help you better understand your disease, know what to expect, and how to manage your treatment experience.

Every person with metastatic uveal melanoma is unique. KIMMTRAK CONNECT provides services and support tailored to your specific needs.

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KIMMTRAK CONNECT®

**You can call KIMMTRAK CONNECT at 844-775-CARE (2273).**

**Available Monday-Friday, 9 AM-7 PM (EST)**

**Additionally, someone is available to help you 24/7.**

**Visit KIMMTRAKCONNECT.com for information and support.**

**"It is so comforting talking to someone who understands my disease. Not everyone knows about this. Your team offers great resources on what to expect with my infusions."**

—KIMMTRAK CONNECT Patient

# KIMMTRAK CONNECT® is here for you (continued)

## Customized support

Your dedicated nurse case manager will help guide you through the services and support we offer.

## Financial assistance

We identify the options that are right for you. Once we understand your needs, we will help set you up with financial assistance.*

* KIMMTRAK CONNECT is not insurance and does not guarantee product coverage or reimbursement.

## Care coordination

Just tell us what you need, and we will try to help you manage your care. We may help coordinate infusion appointments once you and your physician choose a treatment location. We may also be able to assist you in locating affordable transportation to and from your treatment.

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# Glossary

- **Chemotherapy (eg, dacarbazine):** Treatment that uses chemicals to kill fast-growing cells (cancer cells) in your body.
- **Cytokine (sigh-toe-kine) release syndrome:** Side effect of immunotherapy. It happens when a large number of cytokines, substances that help direct your body's immune response, are released into the blood. Symptoms may include fever, tiredness or weakness, vomiting, chills, dizziness, light-headedness, headache, wheezing, and trouble breathing.
- **HLA-A*02:01 target:** A target found on uveal melanoma tumor cells in those who are HLA-A*02:01 positive.
- **Human leukocyte (loo-ko-site) antigen (HLA):** Set of genes that may help the immune system find and destroy cancer.
- **Immune system:** A complex network of cells, tissues, organs, and the molecules they produce that work together to help your body fight infections and other disease.
- **Immunotherapy:** A type of therapy that works along with your own immune system to help the body fight cancer and other diseases.
- **IV infusion:** A way to give fluids, medicine, or nutrients directly into the bloodstream through a vein.
- **Median overall survival:** A statistic that refers to how long patients survive after a particular treatment. It represents when half of the patients are expected to be alive.
- **Metastatic uveal (YOO-vee-uhl) melanoma:** Occurs when the cancer that starts in the eye spreads to other parts of the body.

## Important Safety Information (continued)

- **Skin reactions.** KIMMTRAK may cause skin reactions that require treatment.

# Glossary

- **Phase 3 clinical trial:** A clinical trial that compares new treatments with the best currently available treatment (standard of care).
- **Primary analysis:** The first set of official results from a study.
- **Radiation therapy:** A type of cancer treatment that uses high doses of radiation (energy) to kill cancer cells.
- **Statistical significance:** A term that means a result is unlikely to be explained solely by chance or random factors.
- **T cell:** A type of immune cell that helps your body fight foreign threats, like viruses and cancer.

**Reminder: KIMMTRAK is not chemotherapy or radiation therapy—it is an immunotherapy that is designed to recruit and activate your T cells to fight uveal melanoma tumor cells.***

* Normal skin cells could also be affected.

## Important Safety Information (continued)

Tell your healthcare provider if you get symptoms of skin reactions—such as rash, itching, or skin swelling—that are severe and do not go away.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and KIMMTRAK Patient Information.

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# Indication and Important Safety Information Including Boxed Warning

## Usage

KIMMTRAK is a prescription medicine used to treat HLA-A*02:01-positive adults with uveal melanoma that cannot be removed by surgery or has spread.

## Important Safety Information

**What is the most important information I should know about KIMMTRAK?**

**KIMMTRAK can cause serious side effects that can be severe or life threatening and usually happen within the first three infusions, including:**

- **Cytokine Release Syndrome (CRS). Symptoms of CRS may include:** fever, tiredness or weakness, vomiting, chills, nausea, low blood pressure, dizziness and light-headedness, headache, wheezing and trouble breathing, rash.

Tell your healthcare provider right away if you get any of these symptoms. Your healthcare provider will check for these problems during treatment with KIMMTRAK. Your healthcare provider may temporarily stop or completely stop your treatment with KIMMTRAK if you have severe side effects.

See **"KIMMTRAK can cause other serious side effects"** for more information.

**Before receiving KIMMTRAK, tell your healthcare provider about all of your medical conditions, including if you:**

- are pregnant or plan to become pregnant. KIMMTRAK may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with KIMMTRAK.

  **For females who are able to become pregnant:**

  - Your healthcare provider should do a pregnancy test before you start treatment with KIMMTRAK.
  - Use an effective form of birth control during treatment with KIMMTRAK and for at least 1 week after the last dose of KIMMTRAK.

- are breastfeeding or plan to breastfeed. It is not known if KIMMTRAK passes into your breast milk. Do not breastfeed during the treatment with KIMMTRAK and for at least 1 week after the last dose of KIMMTRAK.

# Indication and Important Safety Information Including Boxed Warning (continued)

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

**KIMMTRAK can cause other serious side effects, including:**

- **Skin reactions.** KIMMTRAK may cause skin reactions that require treatment. Tell your healthcare provider if you get symptoms of skin reactions—such as rash, itching, or skin swelling—that are severe and do not go away.
- **Abnormal liver blood tests.** Your healthcare provider will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK. Tell your healthcare provider if you get symptoms of liver problems such as right-sided abdominal pain or yellowing of the skin or eyes.

**The most common side effects of KIMMTRAK include:**

- cytokine release syndrome (CRS)
- rash
- fever
- itching
- tiredness
- nausea
- chills
- stomach pain
- swelling
- low blood pressure (symptoms may include dizziness or light-headedness)
- dry skin
- headache
- vomiting
- abnormal liver blood tests

These are not all the side effects possible with KIMMTRAK.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088).

Please read the accompanying Patient Information Leaflet before you receive KIMMTRAK and discuss any questions you have with your healthcare provider.

**Please see KIMMTRAK Patient Information.**

# Living longer is an important treatment goal, and KIMMTRAK provided that possibility*

In the clinical trial, **73% (184 out of 252) of KIMMTRAK patients were alive at 1 year** compared to 59% (74 out of 126) of patients who received other treatments.†

Treatment-related **side effects were generally predictable** (expected to occur) and were managed with certain medications.

Ask your doctor about getting the **HLA-A*02:01 blood test** to determine if you are eligible for KIMMTRAK.

* Compared with other immunotherapies or chemotherapy.

† Other treatments studied in the trial included immunotherapies (pembrolizumab or ipilimumab) or chemotherapy (dacarbazine).

**Visit KIMMTRAK.com to learn more.**

## Important Safety Information (continued)

**What is the most important information I should know about KIMMTRAK?**

**KIMMTRAK can cause serious side effects that can be severe or life threatening and usually happen within the first three infusions, including:**

- **Cytokine Release Syndrome (CRS). Symptoms of CRS may include:** fever, tiredness or weakness, vomiting , chills, nausea, low blood pressure, dizziness and light-headedness, headache, wheezing and trouble breathing, rash.

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