



KYMRIAH[®]

(tisagenlecleucel) Suspension
for IV infusion

An introduction to KYMRIAH THERAPY

**THE FIRST
FDA-APPROVED
CAR-T**
for patients up to
25 years of age with
relapsed/refractory ALL

Approved Use

What is KYMRIAH?

KYMRIAH[®] (tisagenlecleucel) is made from your own white blood cells and is a prescription cancer treatment used in patients up to 25 years of age who have acute lymphoblastic leukemia (ALL) that has relapsed (went into remission, then came back) or is refractory (did not go into remission with other leukemia treatments).

Important Safety Information

What is the most important information I should know about KYMRIAH?

KYMRIAH may cause side effects that are severe or life-threatening, such as cytokine release syndrome (CRS) and neurological toxicities. Call your health care provider or get emergency help right away if you get any of the following signs and symptoms of:

• Cytokine Release Syndrome:

- | | | |
|----------------------------------|-------------------------------|---------------------------------|
| ◦ Difficulty breathing | ◦ Severe nausea, vomiting, | ◦ Very low blood pressure |
| ◦ Fever (100.4°F/38°C or higher) | diarrhea | ◦ Dizziness/
lightheadedness |
| ◦ Chills/shaking chills | ◦ Severe muscle or joint pain | |

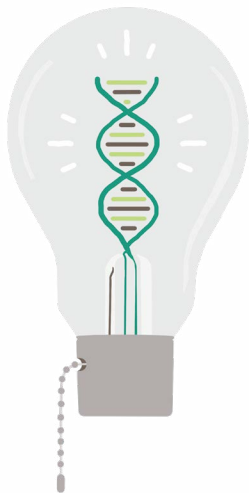
Please see additional Important Safety Information throughout and Summary of Important Safety Information on pages 22 and 23.

An innovative kind of treatment

Finding out that your cancer has returned or hasn't responded to treatment can be devastating. However, recent advancements in treatment have led to more options. Learning about these treatments can help you navigate your next steps.

This brochure will explain an innovative treatment that uses your own immune system to fight your cancer.

Read on to learn more about KYMRIA[®] (tisagenlecleucel).



KYMRIA[®] is a type of immunotherapy for patients with relapsed or refractory B-cell ALL whose previous treatments have not kept their cancer in remission.

Important Safety Information (continued)

What is the most important information I should know about KYMRIA[®]? (continued)

• Neurological Toxicities:

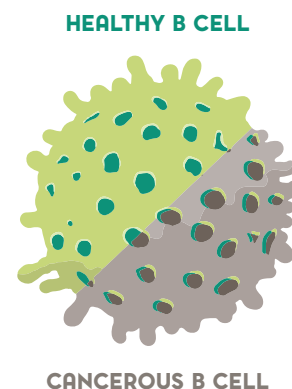
- | | | |
|--------------------------------------|-------------|---|
| ◦ Altered or decreased consciousness | ◦ Confusion | ◦ Difficulty speaking and understanding |
| ◦ Delirium | ◦ Agitation | ◦ Loss of balance |
| | ◦ Seizures | |

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What is B-cell ALL?

B cells are defenders of your body. Along with other cells, they make up your body's immune system. When B cells become cancerous, they can grow out of control and cause a type of blood cancer called B-cell acute lymphoblastic leukemia (ALL). While many patients with leukemia get better after their first treatment, some may not.



What does relapsed/refractory mean?

About 20% of patients with B-cell ALL will not have success with initial treatments. This means either their cancer has returned (relapsed) or their cancer did not respond to treatment (refractory).

In the past, the only choices for patients with relapsed or refractory B-cell ALL were chemotherapy, radiation, or stem cell transplant. But there have been advancements in different types of treatment options, including KYMRIA[®] (tisagenlecleucel).

A glossary of terms is included on [page 21](#) of this brochure to help you understand words you may not have heard before.

Important Safety Information (continued)

What is the most important information I should know about KYMRIA[®]? (continued)

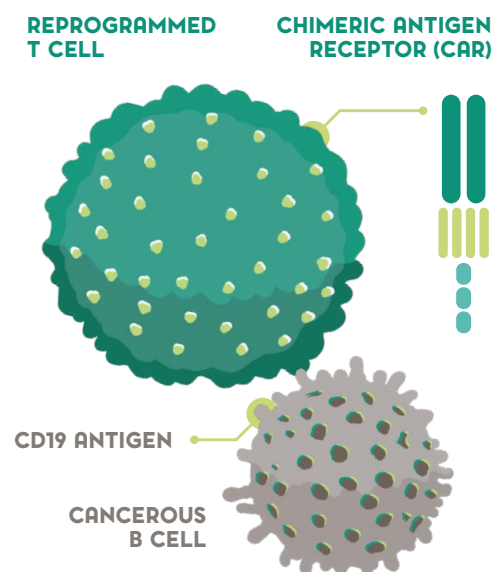
You may be admitted to the hospital and treated with other medications if you have any of these side effects. If you are admitted to the hospital, tell the health care provider that you have received KYMRIA[®].

Because of the risk of CRS and neurological toxicities, KYMRIA[®] is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIA[®] REMS.

What is KYMRIA[®]?

KYMRIA[®] is a type of cutting-edge immunotherapy that uses the power of your own immune system to treat your cancer. KYMRIA[®] is not a pill, chemotherapy, or stem cell transplant. It is a type of treatment called CAR-T. The **CAR** in **CAR-T** stands for chimeric antigen receptor, and the **T** stands for T cell.

KYMRIA[®] enhances the ability of your T cells to detect and destroy your B cells



- Your immune system includes T cells, which are natural defenders of the body
- T cells detect and destroy infected or cancerous cells by looking for certain antigens
- Antigens are markers on cells that help your immune system identify normal cells from infected or cancerous cells; however, your cancerous B cells look like normal B cells, so your T cells don't always recognize them
- KYMRIA[®] reprograms your own T cells into CAR-T cells, which allows them to recognize the CD19 antigen on the surface of your B cells. Your new CAR-T cells can destroy the cancerous and other B cells they could not find before

Because KYMRIA[®] uses your own T cells, you may hear it referred to as an “individualized” therapy. After being treated with KYMRIA[®], you may not need any other treatment for your cancer, though you will continue to be closely monitored by your doctor.

Is KYMRIAHA right for me?

KYMRIAHA® (tisagenlecleucel) is approved to treat children and young adults whose B-cell ALL is refractory or in second or later relapse.

Talk with your doctor about KYMRIAHA

If your treatment isn't working and your cancer has returned, KYMRIAHA might be an appropriate next step. It's important to talk with your doctor early in the process. Your doctor may ask you questions about your treatment history and overall health to determine if you can receive KYMRIAHA.

Topics to discuss with your doctor:

- Your treatment history
- Your cancer's past response to chemotherapy
- Any previous stem cell transplants
- Other conditions you may have
- All current medications, including supplements or steroids
- What tests are needed to make sure KYMRIAHA is right for you



Important Safety Information (continued)

What are other serious side effects of KYMRIAHA?

- **Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS):** Be sure to discuss with your health care provider the possibility of developing this life-threatening condition, and thereafter, your doctor will monitor you for the possibility of developing HLH/MAS

What makes KYMRIAHA different from other therapies?



KYMRIAHA is different from other cancer therapies because it is an **individualized therapy made just for you**. KYMRIAHA is a CAR-T therapy that uses the power of your own immune system to fight your cancer.

- Even if you aren't in remission, you can start KYMRIAHA therapy
- KYMRIAHA is typically given in a single infusion, unlike other treatments delivered more than once
- KYMRIAHA uses a short course of chemotherapy to prepare your body for infusion
- Because KYMRIAHA uses your own cells, you do not need a donor

Please see [page 12](#) of this brochure for more information about the side effects of KYMRIAHA.

Important Safety Information (continued)

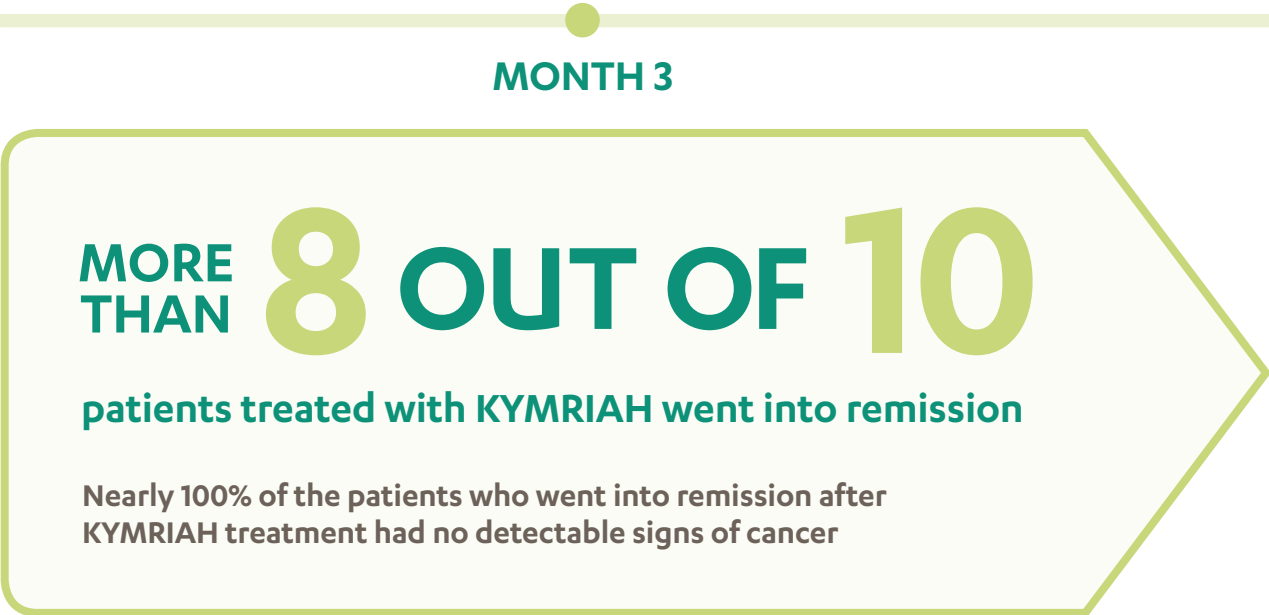
What are other serious side effects of KYMRIAHA? (continued)

- **Allergic Reactions:** Serious allergic reactions, including anaphylaxis, which is a life-threatening allergic reaction, may occur after you receive KYMRIAHA. Some signs and symptoms may include difficulty breathing, very low blood pressure, dizziness, swelling under skin, rash, nausea, and vomiting. You should seek emergency medical treatment right away if you have an allergic reaction

How well does KYMRIAHA work?

KYMRIAHA® (tisagenlecleucel) was originally studied in a global clinical trial of children and young adults with relapsed or refractory B-cell ALL, with many achieving an early and lasting remission. While many patients have been successfully treated with KYMRIAHA, not all patients will respond the same way.

The goal of KYMRIAHA therapy is long-term remission of your cancer



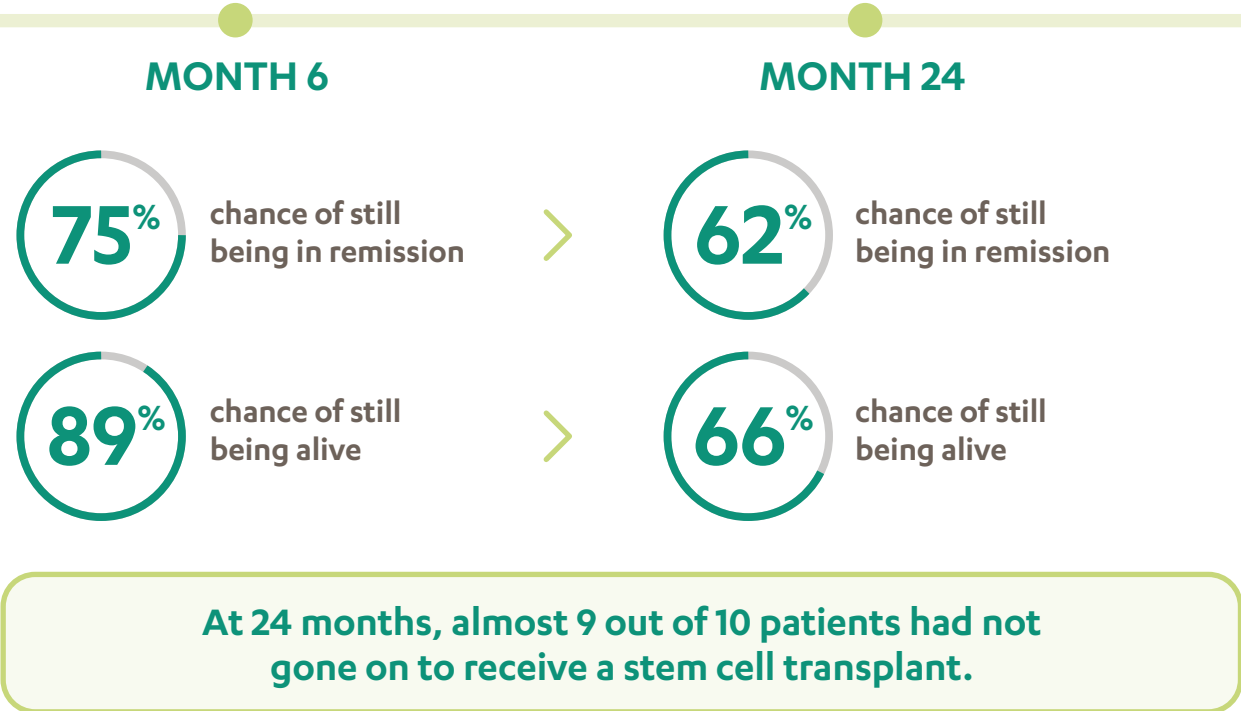
Important Safety Information (continued)

What are other serious side effects of KYMRIAHA? (continued)

- **Serious Infections:** KYMRIAHA can increase the risk of life-threatening infections that may lead to death. Tell your health care provider right away if you develop fever, chills, or any signs or symptoms of an infection

What are the long-term results?

Since KYMRIAHA was approved, patients from the clinical trial have been followed to see how well they do over the course of years. A long-term follow-up of patients in the clinical trial was done at 24 months from the date of infusion of KYMRIAHA.

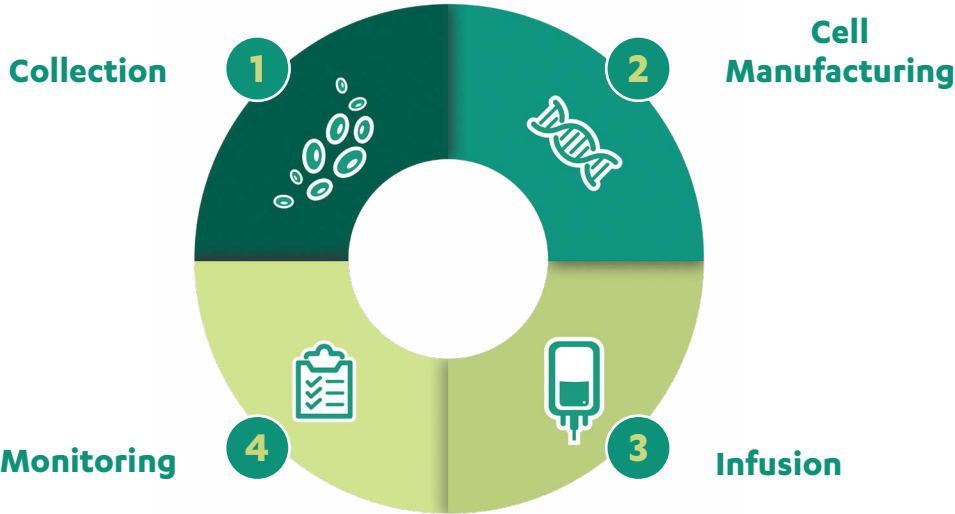


Important Safety Information (continued)

What are other serious side effects of KYMRIAHA? (continued)

- **Prolonged Low Blood Cell Counts (Cytopenia):** KYMRIAHA can lower 1 or more types of your blood cells (red blood cells, white blood cells, or platelets). After treatment, your health care provider may test your blood to check cell counts. Tell your health care provider right away if you get a fever or other symptoms of an infection, are feeling tired, weak, or short of breath, or have unusual bruising or bleeding

What is the process for getting KYMRIA?



- 1

Collection

First, your doctor takes some of your blood to collect your T cells. This T cell collection process is called leukapheresis (loo-kuh-fuh-REE-sis), which usually takes 3 to 6 hours.
- 2

Cell Manufacturing

Your collected T cells will be reprogrammed into KYMRIA® (tisagenlecleucel) CAR-T cells at a specialized manufacturing facility. The process usually takes 3 to 4 weeks, but timing and manufacturing outcomes can vary. Your treatment team can help guide you through the process.

Important Safety Information (continued)

What are other serious side effects of KYMRIA? (continued)

- **Hypogammaglobulinemia:** A condition in which the level of immunoglobulins (antibodies) in your blood is low and the risk of infection is increased. It is expected that you may develop hypogammaglobulinemia with KYMRIA, and you may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with KYMRIA. Tell your health care provider about your treatment with KYMRIA before receiving a live vaccine
- **Secondary Cancers:** After treatment with KYMRIA, your health care provider will monitor you for the rest of your life, as you may develop secondary cancers or recurrence of your leukemia

10 Please see additional Important Safety Information throughout and Summary of Important Safety Information on pages 22 and 23.

- 3

Infusion

About 2 to 14 days before your CAR-T cells are ready, you will receive a short course of chemotherapy over 4 days that helps prepare your body to receive your reprogrammed KYMRIA CAR-T cells.

Once your treatment team decides you are ready, you will receive your CAR-T cells through an infusion that takes less than 30 minutes.
- 4

Monitoring

In the short term, regular monitoring to manage side effects is important. Whether you received your infusion in an inpatient or outpatient setting, it will be necessary to stay close to the hospital for at least 4 weeks after receiving KYMRIA.

In the long term, your treatment team will establish a monitoring plan for ongoing follow-ups. The US Food and Drug Administration (FDA) recommends that all patients who are treated with KYMRIA be followed for 15 years after infusion. Your treatment team will offer you participation in a long-term registry conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) for this follow-up. This information is used to help future patients and contributes to the understanding of the effects of CAR-T cell therapy.

Your treatment team will be there to help guide you through the process.

Important Safety Information (continued)

What are other serious side effects of KYMRIA? (continued)

- **Effects on Ability to Drive and Use Machines:** Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get KYMRIA because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures

What side effects may I experience with KYMRIA®?

KYMRIA® (tisagenlecleucel) may cause side effects that are severe or life-threatening. Your treatment team is specially trained to monitor for and manage these potential side effects. Most side effects happen in the weeks following infusion with KYMRIA.

Get help immediately if you experience any of the following:

- Difficulty breathing
- Fever (100.4°F/38°C or higher)
- Chills/shaking chills
- Confusion
- Severe muscle or joint pain
- Very low blood pressure
- Dizziness/lightheadedness
- Severe nausea, vomiting, diarrhea



Cytokine Release Syndrome

Cytokine release syndrome (CRS) may occur when your immune system becomes highly active. It is the most common and expected side effect of KYMRIA, as well as other CAR-T therapies. Symptoms range from fever or low blood pressure to irregular or rapid heartbeat. CRS may be associated with liver, kidney, and heart dysfunction and bleeding disorders.

Most patients in the clinical trial experienced CRS, usually within 10 days after infusion. Your treatment team will check your progress after infusion. Members of your team are trained to recognize the symptoms of CRS and have specific medicines to treat it.

Neurological Events

KYMRIA may also have effects on the central nervous system, making you feel confused, agitated, dizzy, or disoriented. More severe symptoms might affect your speech or consciousness or cause seizures. Be sure to tell your treatment team right away if you experience any neurological symptoms. Most neurological events went away on their own in the clinical trials.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS)

Presenting signs and symptoms are similar to those of CRS and infections.

Prolonged Low Blood Cell Counts (Cytopenia)

KYMRIA may cause a condition called cytopenia. This is when you have low levels of 1 or more types of blood cells. Your treatment team will do blood tests to check all your blood cell counts after treatment with KYMRIA. Cytopenia that lasts a long time (prolonged) may increase your risk of infection. Cytopenia will be monitored, and your treatment team is prepared to manage it. Tell your doctor right away if you get a fever, are feeling tired, or have bruising or bleeding.

Low Antibody Levels (Hypogammaglobulinemia)

Because KYMRIA CAR-T cells are designed to detect and destroy your B cells, they will also attack the normal B cells in your body. B cells defend your body by producing antibodies. Antibodies bind to invaders so other immune cells can destroy them.

After KYMRIA, you may have fewer normal B cells and, therefore, fewer antibodies. A low level of antibodies in your blood is a condition called hypogammaglobulinemia (HY-po-GAM-muh-GLOB-u-lin-EEM-ee-uh). If untreated, a low antibody level may increase your risk for infections. Your treatment team can manage this with antibody replacement medications (for example, intravenous immunoglobulin infusions, also known as IVIG infusions). Hypogammaglobulinemia can last for a long time, so regular IVIG infusions may be needed. Tell your doctor right away if you develop signs or symptoms of an infection.

Effects on Ability to Drive and Use Machines

Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get KYMRIA because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures.

Most Common Side Effects of KYMRIA are:

- Difficulty breathing
- Fever (100.4°F/38°C or higher)
- Chills/shaking chills
- Confusion
- Severe nausea, vomiting, diarrhea
- Severe muscle or joint pain
- Very low blood pressure
- Dizziness/lightheadedness
- Headache

Please note that these are not all the possible side effects of KYMRIA treatment. Talk to your treatment team about other possible side effects and how to manage them.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

What is the KYMRIA® REMS program?

A **risk evaluation and mitigation strategy (REMS)** is a program to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of the drug outweigh its risks. Because of the risk of cytokine release syndrome and neurological toxicities, the FDA has required a REMS for KYMRIA® (tisagenlecleucel). KYMRIA is only available through select treatment centers participating in the KYMRIA REMS Program.

The KYMRIA REMS Program Patient Wallet Card

As part of the KYMRIA REMS Program, you will be given a wallet card either before or at the time of receiving a KYMRIA infusion. Be sure to carry your completed wallet card with you at all times.

PATIENT WALLET CARD

Have This Card With You At All Times
Show It To Any Doctor That Sees You And When You Go To The Hospital

You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting Kymriah. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.

Visit www.KYMRIA-REMS.com to learn more about the program or to download a replacement card if needed.

Important Safety Information (continued)

How will I get KYMRIA?

- Since KYMRIA is made from your own white blood cells, your health care provider has to take some of your blood. This is called “leukapheresis.” It takes 3 to 6 hours and may need to be repeated. A tube (intravenous catheter) will be placed in your vein to collect your blood
- Your blood cells are frozen and sent to the manufacturing site to make KYMRIA. It takes about 3 to 4 weeks from the time your cells are received at the manufacturing site and shipped to your health care provider, but the time may vary
- While waiting for KYMRIA to be made, your health care provider may give you therapy to stabilize your cancer
- In addition, before you get KYMRIA, your health care provider may give you chemotherapy for a few days to prepare your body. When your body is ready, your health care provider will give you KYMRIA through a tube (intravenous catheter) in your vein. This usually takes less than 1 hour
- You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting KYMRIA. Your health care provider will check to see if your treatment is working and help you with any side effects that occur

What kind of support is available?

Whether you have questions about KYMRIA, treatment center locations, or insurance coverage, **KYMRIA CARES™** is here to help.



Please call **1-844-4KYMRIA (1-844-459-6742)** to learn more.

Support comes in many forms

No matter how positive or strong you are, cancer treatment can be stressful for everyone involved. It is important to seek care for not only your physical health, but also your mental and emotional well-being.

- Know that it is okay to ask for help. Establish a support network of family, friends, and/or religious or spiritual groups
- Consider counseling services for yourself
- Maintain a schedule to help bring a sense of normalcy, with planned times for meals, homework, or entertainment
- Keep in mind that no 2 cancer experiences are the same and that your family and friends may cope with your cancer differently
- Remember to make room for fun. Take time to do something you like, such as meet a friend for coffee, see a movie, etc

Important Safety Information (continued)

What are the possible or reasonably likely side effects of KYMRIA?

The most common side effects of KYMRIA include:

- | | | |
|----------------------------------|-------------------------------------|-----------------------------|
| • Difficulty breathing | • Confusion | • Very low blood pressure |
| • Fever (100.4°F/38°C or higher) | • Severe nausea, vomiting, diarrhea | • Dizziness/lightheadedness |
| • Chills/shaking chills | • Severe muscle or joint pain | • Headache |

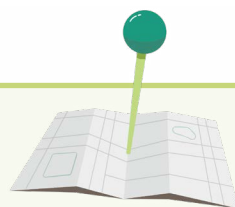
These are not all the possible side effects of KYMRIA. Talk to your health care provider for medical advice about side effects.

How do I learn more about KYMRIAH?

You and your treatment team will discuss the KYMRIAH® (tisagenlecleucel) therapy process. Talk with your treatment team about any questions you may have.

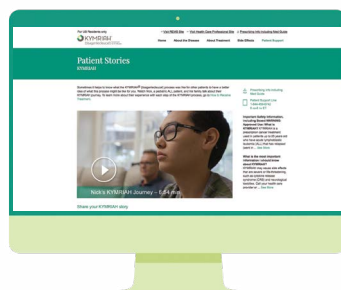
To learn more, visit [KYMRIAH.com](https://www.kymriah.com) for educational materials and frequently asked questions.

[KYMRIAH.com](https://www.kymriah.com) offers an interactive map to help you find certified treatment centers in the United States.



Share your KYMRIAH story

Sometimes hearing other patients' experiences with relapsed or refractory B-cell ALL can make all the difference to a new patient. If you would like to share your story, please call **1-844-606-3339** or email ShareYourStory@inspired-patients.com.



[KYMRIAH.com](https://www.kymriah.com)

Watch other patients and their families talk about their experiences with KYMRIAH.

Like us on Facebook

Explore our Facebook page at [Facebook.com/KYMRIAH](https://www.facebook.com/KYMRIAH) and check back frequently to view new posts.

Important Safety Information (continued)

What should I tell my health care provider before receiving KYMRIAH?

- Tell your health care provider if you are pregnant, planning to be pregnant, or breastfeeding. Your health care provider may do a pregnancy test prior to your starting treatment. No information is available of KYMRIAH use in pregnant or breastfeeding women. Therefore, KYMRIAH is not recommended for women who are pregnant or breastfeeding. Talk to your health care provider about birth control and pregnancy
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

Additional support resources



American Cancer Society | www.Cancer.org

The American Cancer Society is committed to attacking cancer from every angle, from launching breakthrough research to empowering patients with resources, information, and support.

CancerCare | www.CancerCare.org

CancerCare provides counseling, support groups, education, and financial assistance to cancer patients and their caregivers.

Cancer Support Community (CSC) | www.CancerSupportCommunity.org

The largest professionally led nonprofit network of cancer support worldwide, the CSC builds community and offers resources to those impacted by cancer.

Leukemia & Lymphoma Society (LLS) | www.LLS.org

The mission of LLS is to cure blood cancers and improve the quality of life of patients and their families.

Support for young adults

B+ Foundation | www.BePositive.org

B+ Foundation focuses on delivering financial assistance, cancer research, awareness, and positivity.

Children's Cancer Cause (CCC) | www.ChildrensCancerCause.org

The CCC works to expand resources and access to better treatments for pediatric patients and their families.

Emily Whitehead Foundation | www.EmilyWhiteheadFoundation.org

Initially founded to support a pediatric cancer patient, this foundation's mission is to raise awareness and funding for innovative childhood cancer treatments.

St. Baldrick's Foundation | www.StBaldricks.org

St. Baldrick's helps raise awareness and funding around childhood cancers.

Stupid Cancer | www.StupidCancer.org

Stupid Cancer is a US-based charity that supports young adults with cancer worldwide by providing information, online community forums, and regional support groups, as well as large-scale summits and meet-ups throughout the year.

The organizations and websites listed on this page are maintained by third parties over whom Novartis Pharmaceuticals Corporation has no control. As such, Novartis Pharmaceuticals Corporation makes no representation as to the accuracy or any other aspect of the information supplied by these organizations or contained in these websites. The organizations listed on this page do not specifically endorse the use of KYMRIAH.

What should I ask my treatment team?

It is important to know who is on your KYMRIA[®] (tisagenlecleucel) treatment team and how to get in touch with them. Remember to ask for names, telephone numbers, email addresses, and any other contact information.

Here are some suggested questions to ask your medical team during each step of your KYMRIA[®] treatment process.

Initial Discussion

- How does my treatment history affect my eligibility for KYMRIA[®]?
- Can I receive KYMRIA[®] if I've already received a stem cell transplant?
- Can I receive a stem cell transplant if I've already received KYMRIA[®]?
- What if I have other health conditions?
- How will I feel throughout the treatment process?
- Where can I receive KYMRIA[®] therapy?
- How long will I need to stay near the treatment center?
- Will my insurance cover KYMRIA[®] therapy?



Ask your doctor for a KYMRIA[®] Patient Binder.

It can help you keep track of important information such as appointments, business cards, emergency numbers, and notes from your discussions with your medical team.

Important Safety Information (continued)

What should I be aware of after receiving KYMRIA[®]?

- Some commercial HIV tests may cause a false positive HIV test result
- Do not donate blood, organs, tissues, sperm, oocytes, and other cells

This is a summary of the most important safety information about KYMRIA[®]. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIA[®] can be found at www.KYMRIA.com, or call 1-844-NVS-CART (1-844-687-2278).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Collection

- How should I prepare for collection?
- How long will it take?
- What can I do during collection?
- Will there be any limitations or side effects afterward?
- How soon after collection will my KYMRIA[®] CAR-T cells be ready for infusion?

Preinfusion Lymphodepleting Chemotherapy

- How is this chemotherapy different from the chemotherapy I previously received?
- How long will it take?
- Will there be side effects?
- How far in advance of my infusion do I receive chemotherapy?

Infusion

- How should I prepare for infusion?
- What will infusion be like?
- How long will it take?

Side Effects and Monitoring

- What side effects should I expect after infusion?
- How will serious side effects be managed after therapy?
- How will I know KYMRIA[®] is working?
- When do I need to check in with my treatment team?
- How long do I need to stay in or near my hospital?
- After returning home, what kind of side effects require a hospital visit?
- How quickly can I get back to my daily routine?



My notes

Use these pages to write down any notes or questions you may have for your treatment team.



Glossary

Here are some definitions of certain terms in this brochure that may be unfamiliar to you.



Antibody: A protein made by your B cells that helps to protect the body against infection.

Antigen: A marker on cells that helps your immune system identify normal cells from infected or cancerous cells.

B cells: Along with other cells, they make up your body's immune system. They defend the body by producing antibodies.

CAR-T cell therapy: A specific type of cancer treatment. The **CAR** in **CAR-T** stands for chimeric antigen receptor, and the **T** stands for T cell.

CD19: An antigen located on your B cells.

Chimeric: Cells coming from genetic materials (such as DNA) that are from more than one organism.

CRS (Cytokine Release Syndrome): A side effect that can happen when the immune system is highly activated.

Immunotherapy: A type of cancer treatment that helps your immune system fight cancer.

IVIG (intravenous immunoglobulin) therapy: An infusion that gives you antibodies to help fight infections and make your immune system stronger.

Leukapheresis: When your doctor takes some of your blood to collect your T cells.

Refractory: Your cancer did not respond to treatment.

Relapsed: Your cancer has returned.

Remission: The signs of your cancer have disappeared, or else your disease is under control. It does not necessarily mean a cure.

T cells: Along with other cells, they make up your body's immune system. They are natural defenders that detect and destroy possible threats such as infected or cancerous cells.

Summary of Important Safety Information

What is KYMRIA®H?

KYMRIA®H (tisagenlecleucel) is made from your own white blood cells and is a prescription cancer treatment used in patients up to 25 years of age who have acute lymphoblastic leukemia (ALL) that is either relapsing (went into remission, then came back) or is refractory (did not go into remission after receiving other leukemia treatments).

What is the most important information I should know about KYMRIA®H?

KYMRIA®H may cause side effects that are severe or life-threatening, such as cytokine release syndrome (CRS) and neurological toxicities. Call your health care provider or get emergency help right away if you get any of the following signs and symptoms of:

- | | |
|-------------------------------------|---|
| • Cytokine Release Syndrome: | • Neurological Toxicities: |
| ◦ Difficulty breathing | ◦ Altered or decreased consciousness |
| ◦ Fever (100.4°F/38°C or higher) | ◦ Delirium |
| ◦ Chills/shaking chills | ◦ Confusion |
| ◦ Severe nausea, vomiting, diarrhea | ◦ Agitation |
| ◦ Severe muscle or joint pain | ◦ Seizures |
| ◦ Very low blood pressure | ◦ Difficulty speaking and understanding |
| ◦ Dizziness/lightheadedness | ◦ Loss of balance |

You may be admitted to the hospital and treated with other medications if you have any of these side effects. If you are admitted to the hospital, tell the health care provider that you have received KYMRIA®H.

Because of the risk of CRS and neurological toxicities, KYMRIA®H is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIA®H REMS.

What are other serious side effects of KYMRIA®H?

- Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS):** Be sure to discuss with your health care provider the possibility of developing this life-threatening condition, and thereafter, your doctor will monitor you for the possibility of developing HLH/MAS
- Allergic Reactions:** Serious allergic reactions, including anaphylaxis, which is a life-threatening allergic reaction, may occur after you receive KYMRIA®H. Some signs and symptoms may include difficulty breathing, very low blood pressure, dizziness, swelling under skin, rash, nausea, and vomiting. You should seek emergency medical treatment right away if you have an allergic reaction
- Serious Infections:** KYMRIA®H can increase the risk of life-threatening infections that may lead to death. Tell your health care provider right away if you develop fever, chills, or any signs or symptoms of an infection
- Prolonged Low Blood Cell Counts (Cytopenias):** KYMRIA®H can lower 1 or more types of your blood cells (red blood cells, white blood cells, or platelets). After treatment, your health care provider may test your blood to check cell counts. Tell your health care provider right away if you get a fever or other symptoms of an infection, are feeling tired, weak, or short of breath, or have unusual bruising or bleeding
- Hypogammaglobulinemia:** A condition in which the level of immunoglobulins (antibodies) in your blood is low and the risk of infection is increased. It is expected that you may develop hypogammaglobulinemia with KYMRIA®H, and you may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with KYMRIA®H. Tell your health care provider about your treatment with KYMRIA®H before receiving a live vaccine
- Secondary Cancers:** After treatment with KYMRIA®H, your health care provider will monitor you for the rest of your life, as you may develop secondary cancers or recurrence of your cancer

- Effects on Ability to Drive and Use Machines:** Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get KYMRIA®H because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures

How will I get KYMRIA®H?

- Since KYMRIA®H is made from your own white blood cells, your health care provider has to take some of your blood. This is called “leukapheresis.” It takes 3 to 6 hours and may need to be repeated. A tube (intravenous catheter) will be placed in your vein to collect your blood
- Your blood cells are frozen and sent to the manufacturing site to make KYMRIA®H. It takes about 3 to 4 weeks from the time your cells are received at the manufacturing site and shipped to your health care provider, but the time may vary
- While waiting for KYMRIA®H to be made, your health care provider may give you therapy to stabilize your cancer
- In addition, before you get KYMRIA®H, your health care provider may give you chemotherapy for a few days to prepare your body. When your body is ready, your health care provider will give you KYMRIA®H through a tube (intravenous catheter) in your vein. This usually takes less than 1 hour
- You should plan to stay within 2 hours of the location where you received your treatment for at least 4 weeks after getting KYMRIA®H. Your health care provider will check to see if your treatment is working and help you with any side effects that occur

What are the possible or reasonably likely side effects of KYMRIA®H?

The most common side effects of KYMRIA®H include:

- | | | |
|----------------------------------|-------------------------------------|-----------------------------|
| • Difficulty breathing | • Confusion | • Very low blood pressure |
| • Fever (100.4°F/38°C or higher) | • Severe nausea, vomiting, diarrhea | • Dizziness/lightheadedness |
| • Chills/shaking chills | • Severe muscle or joint pain | • Headache |

These are not all the possible side effects of KYMRIA®H. Talk to your health care provider for medical advice about side effects.

What should I tell my health care provider before receiving KYMRIA®H?

- Tell your health care provider if you are pregnant, planning to be pregnant, or breastfeeding. Your health care provider may do a pregnancy test prior to your starting treatment. No information is available of KYMRIA®H use in pregnant or breastfeeding women. Therefore, KYMRIA®H is not recommended for women who are pregnant or breastfeeding. Talk to your health care provider about birth control and pregnancy
- Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

What should I be aware of after receiving KYMRIA®H?

- Some commercial HIV tests may cause a false positive HIV test result
- Do not donate blood, organs, tissues, sperm, oocytes, and other cells

This is a summary of the most important safety information about KYMRIA®H. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIA®H can be found at www.KYMRIA®H.com, or call 1-844-NVS-CART (1-844-687-2278).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.



KYMRIAH CARES®



Have questions?

Whether you have questions about KYMRIAH® (tisagenlecleucel), treatment center locations, or insurance coverage, **KYMRIAH CARES™** is here to help.

Please call **1-844-4KYMRIAH**
(1-844-459-6742) to learn more.

To learn more about KYMRIAH,
talk to your doctor
or visit [KYMRIAH.com](https://www.kymriah.com)



Please see additional Important Safety Information throughout and Summary of Important Safety Information on pages 22 and 23.



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