



I AM KYMRIAH

Robyn: actual KYMRIAH CAR-T patient

Approved Use

What is KYMRIAH?

KYMRIAH® (tisagenlecleucel) is made from your own white blood cells and is a prescription cancer treatment used in patients with large B-cell lymphoma, a type of non-Hodgkin lymphoma, that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least two other kinds of treatment.

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

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

 **KYMRIAH**[®]
(tisagenlecleucel) Suspension
for IV infusion

WHAT IS RELAPSED/REFRACTORY DLBCL?

The immune system is made up of different cells and organs that work together to protect the body from diseases. For example, there are B cells, T cells, and glands called lymph nodes. Sometimes the cells inside a lymph node can grow abnormally and become cancerous.

DLBCL is a type of non-Hodgkin lymphoma that affects the cells and organs of the immune system. In the United States, DLBCL is the most common type of non-Hodgkin lymphoma. There are different types of DLBCL, including high-grade B-cell lymphoma and DLBCL that arises from follicular lymphoma. Patients with DLBCL have abnormal (cancerous) B cells in their lymph nodes, and potentially in other parts of the body. Patients' cancer is considered **relapsed** when they have gone into remission but their cancer has come back, or **refractory** when they are not responding to treatment.

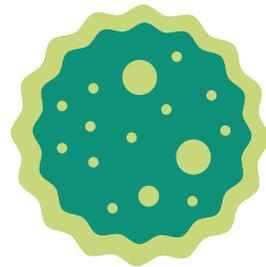
DLBCL, diffuse large B-cell lymphoma.

Important Safety Information (continued)

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

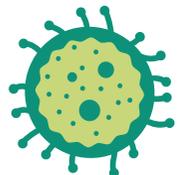
• Neurological Toxicities:

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



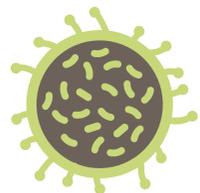
T cell

T cells are a key part of your immune system that can find and destroy cells that are infected or that have become cancerous.



B cell

B cells are also a key component of your immune system. They make special proteins called antibodies, which attach to the surface of foreign invaders, alerting your body to the presence of intruders. Some B cells can then remember the intruders so if they see them again in the future, they can respond more quickly.



Cancerous B cell

Your healthy B cells can sometimes change and develop into a cancer, including DLBCL. These abnormal B cells continue to grow and increase in number, which can affect your body in different ways.

KYMRIA[®] CAREGIVERS

The family and friends of patients with cancer play an important role in their treatment experience. If you are caring for someone with relapsed or refractory DLBCL, **look for the KYMRIA[®] Caregivers boxes throughout this brochure.** Also refer to our website, www.KYMRIA.com, and other support materials for more information on how best to support your loved one during this time.



KYMRIA[®] CAREGIVERS

Finding out your loved one's cancer has returned or hasn't responded to treatment can be hard on everyone's mental and emotional well-being. It is important to tap into available resources and practice self-care during this difficult time. Leaning on social and emotional support networks, engaging in physical activity, and connecting with spirituality can be helpful. See pages 14 and 15 for more information and support.

Important Safety Information (continued)

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

 **KYMRIA[®]**
(tisagenlecleucel) Suspension
for IV infusion

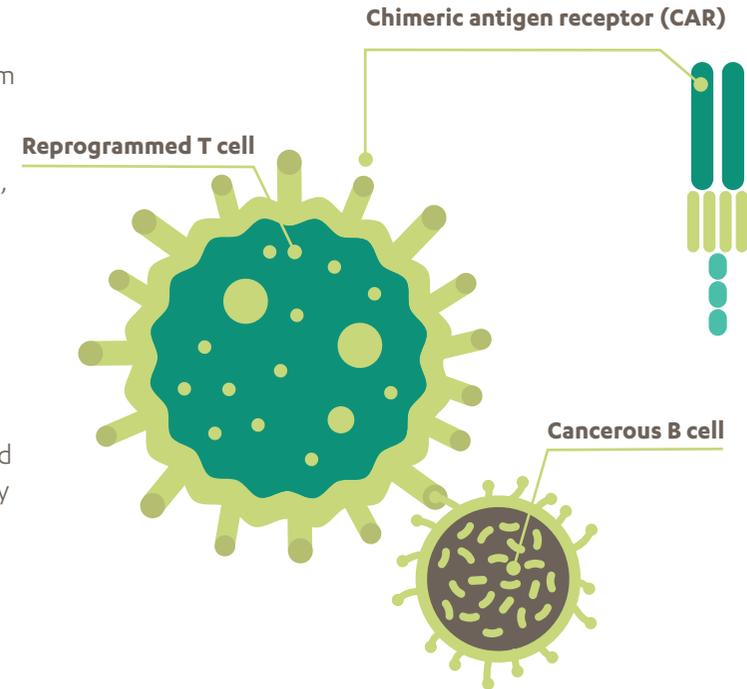
WHAT IS KYMRIA[®]?

Learning that your cancer has returned or isn't responding to treatment is devastating. However, there may be another option that is different from what you've been treated with in the past. KYMRIA[®] (tisagenlecleucel) is a therapy specifically made for patients like you, with relapsed or refractory DLBCL. Unlike traditional chemotherapy or stem cell transplant, KYMRIA is a type of immunotherapy called **CAR-T cell therapy**.

CAR-T cell therapy harnesses the power of your own T cells—which naturally recognize and fight foreign invaders but sometimes need some additional help.

KYMRIA is made up of your own T cells that have been reprogrammed to be better at detecting and destroying the cancerous B cells in your body. Your T cells will be able to recognize an antigen on your B cells called CD19. Antigens are markers on cells that help your immune system identify normal cells from infected or cancerous cells.

CAR, chimeric antigen receptor.



Important Safety Information (continued)

What are other serious side effects of KYMRIA[®]?

- **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

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

KYMRIA is an individualized therapy that uses the power of your own immune system to fight your cancer. Here's some information about receiving KYMRIA:



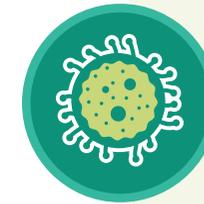
If your cancer has returned and/or isn't responding to other treatments, KYMRIA may be right for you. You do not have to be in remission (or get into remission) to begin KYMRIA therapy.



Your physician may decide to give you a short course of chemotherapy before receiving KYMRIA. This prepares your body for new CAR-T cells.



KYMRIA is given in a single infusion.



KYMRIA enhances the ability to detect and destroy your healthy and cancerous B cells.

Important Safety Information (continued)

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

- **Allergic Reactions:** Serious allergic reactions, including anaphylaxis, which is a life-threatening allergic reaction, may occur after you receive KYMRIA. 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

 **KYMRIA[®]**
(tisagenlecleucel) Suspension
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IS KYMRIA[®] RIGHT FOR ME?

KYMRIA[®] (tisagenlecleucel) is a treatment used in patients with non-Hodgkin lymphoma, including DLBCL, who have relapsed or are refractory after having at least 2 other kinds of treatment. If you are considering treatment options, talk to your doctor about KYMRIA[®].

Topics to discuss with your doctor:

- Your treatment history, including if you have had previous stem cell transplants
- Your cancer's response to previous therapies
- All current medications, including any supplements or steroids
- Other medical conditions you may have
- What tests are needed to make sure KYMRIA[®] is right for you



KYMRIA[®] CAREGIVERS

Be prepared to help with doctor discussions. Whether you're preparing your loved one ahead of time or learning some of his or her medical history for yourself, it's useful to keep a little notebook with information you think will be important.

Important Safety Information (continued)

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

- **Serious Infections:** KYMRIA[®] 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

WILL KYMRIA[®] PUT MY CANCER INTO REMISSION?

The goal of KYMRIA[®] is to put your cancer into long-term remission. Many patients with DLBCL have had lasting responses to treatment. Keep in mind that every patient is unique and responses to treatment may vary depending on the individual.

In an international, phase 2 pivotal study (JULIET), high rates of long-lasting responses were seen with the use of KYMRIA[®]

Overall Response Rate
of adults
responded
to treatment
with KYMRIA[®]
50%
(34 of 68)

IN THE MAJORITY OF PATIENTS WHO
ACHIEVED A RESPONSE, THE RESPONSE
WAS GENERALLY ONGOING

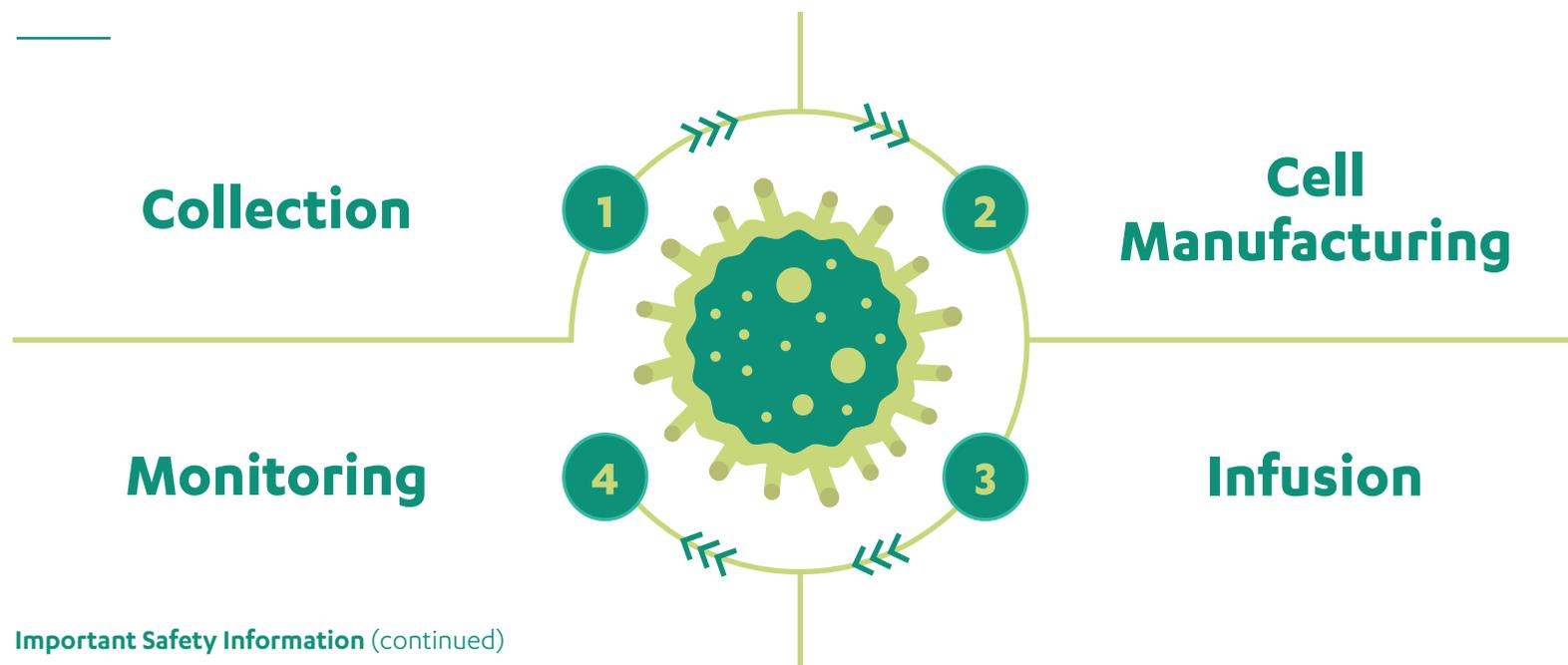
Important Safety Information (continued)

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

- **Prolonged Low Blood Cell Counts (Cytopenias):** KYMRIA[®] 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

 **KYMRIA[®]**
(tisagenlecleucel) Suspension
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WHAT IS THE PROCESS FOR GETTING KYMRIAHA?



Important Safety Information (continued)

What are other serious side effects of KYMRIAHA? (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 KYMRIAHA® (tisagenlecleucel), and you may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with KYMRIAHA. Tell your health care provider about your treatment with KYMRIAHA before receiving a live vaccine

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1 Collection

Your T cells will be collected through a process 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 CAR-T cells at a specialized manufacturing facility. The process usually takes 3 to 4 weeks, but timing and manufacturing outcomes can vary.

3 Infusion

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

Before your infusion, your physician will decide if you need a short course of chemotherapy to help prepare your body for your CAR-T cells.

Important Safety Information (continued)

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

- **Secondary Cancers:** After treatment with KYMRIAHA, your health care provider will monitor you for the rest of your life, as you may develop secondary cancers or recurrence of your cancer

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 your treatment center for at least 4 weeks after receiving KYMRIAHA.

In the long term, your treatment team will establish a monitoring plan for ongoing follow-ups. The Food and Drug Administration (FDA) recommends that all patients who are treated with KYMRIAHA 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.

 **KYMRIAHA®**
(tisagenlecleucel) Suspension for IV infusion

WHAT SIDE EFFECTS MAY I EXPERIENCE?

KYMRIAH® (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 KYMRIAH.

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 KYMRIAH, 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

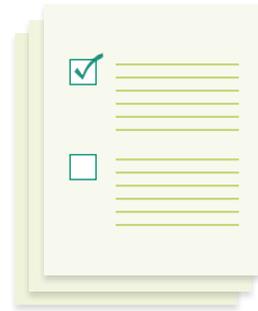
KYMRIAH may also have effects on the central nervous system, making you feel confused, agitated, dizzy, or disoriented. More severe symptoms might affect your speech or consciousness or cause seizures. Be sure to tell your treatment team right away if you experience any neurological symptoms. Most neurological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

KYMRIAH 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 KYMRIAH. 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 KYMRIAH 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 KYMRIAH, 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.

Most Common Side Effects of KYMRIAH 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

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 KYMRIAH because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures.

Please note that these are not all the possible side effects of KYMRIAH 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 KYMRIAHA 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 KYMRIAHA® (tisagenlecleucel). KYMRIAHA is only available through select treatment centers participating in the KYMRIAHA REMS Program.



THE KYMRIAHA REMS PROGRAM PATIENT WALLET CARD

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

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

REMS, risk evaluation and mitigation strategy.

Important Safety Information (continued)

What are other serious side effects of KYMRIAHA? (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 KYMRIAHA because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures

AS A CAREGIVER, HOW CAN I HELP AFTER INFUSION?

KYMRIAHA CAREGIVERS

You can help by watching for side effects. KYMRIAHA can be given in an inpatient (stay in the center) or outpatient (leave center after infusion) setting. Before leaving the treatment center, your treatment team will give you a list of potential side effects to watch for, as well as instructions for what to do if they happen.

KYMRIAHA is only available at select treatment centers. These centers have been specially certified in how to manage the risks of cytokine release syndrome and neurological toxicities.

This is why it will be necessary to stay close to your treatment center for at least 4 weeks after receiving KYMRIAHA.



Important Safety Information (continued)

How will I get KYMRIAHA?

- Since KYMRIAHA 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



WHAT KIND OF SUPPORT IS AVAILABLE?

For information about financial assistance, patient support programs, or finding a treatment center, there is



If you have questions, **KYMRIAH CARES™** can help. Call **1-844-4KYMRIAH** (1-844-459-6742) to learn more.

Important Safety Information (continued)

How will I get KYMRIAH? (continued)

- Your blood cells are frozen and sent to the manufacturing site to make KYMRIAH® (tisagenlecleucel). 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 KYMRIAH to be made, your health care provider may give you therapy to stabilize your cancer



KYMRIAH CAREGIVERS

Cancer treatment can be stressful for everyone involved. It's important to seek care for not only physical health, but also mental and emotional well-being.

If you are caring for a friend or family member with cancer:

- 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 and for those close to you
- Use a binder to help organize appointment reminders, business cards, and emergency telephone numbers
- Keep in mind that no 2 cancer experiences are the same and that patients, families, and caregivers may cope with cancer differently
- Remember to care for your own health and wellness. When you are your best self, you are the best caregiver you can be. Remember to take the time for self-care and do what is important to you

Important Safety Information (continued)

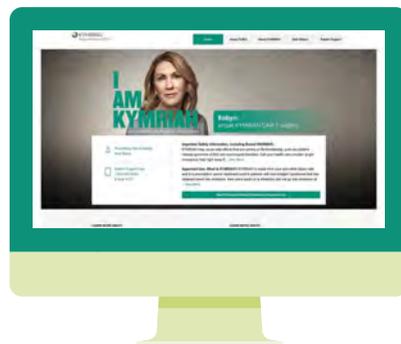
How will I get KYMRIAH? (continued)

- In addition, before you get KYMRIAH, 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 KYMRIAH 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 KYMRIAH. Your health care provider will check to see if your treatment is working and help you with any side effects that occur



HOW DO I LEARN MORE ABOUT KYMRIAHA?

Making treatment decisions for relapsed or refractory DLBCL can be challenging. Talk with your treatment team about questions you may have.



Visit KYMRIAHA.com

to learn more about KYMRIAHA® (tisagenlecleucel), treatment centers, and available support.



Like us on Facebook

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

Important Safety Information (continued)

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

The most common side effects of KYMRIAHA include:

- 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

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

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ADDITIONAL PATIENT SUPPORT RESOURCES



American Cancer Society
www.Cancer.org



Friends of Cancer Research
www.FOCR.org



Patient Advocate Foundation
www.PatientAdvocate.org



CancerCare
www.CancerCare.org



Leukemia & Lymphoma Society
www.LLS.org



St. Baldrick's Foundation
www.StBaldricks.org



Cancer Research Institute
www.CancerResearch.org



Lymphoma Research Foundation
www.Lymphoma.org



Stupid Cancer
www.StupidCancer.org



Cancer Support Community
www.CancerSupportCommunity.org

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SHARE YOUR STORY



Sometimes hearing other families' experiences with relapsed or refractory DLBCL can make all the difference. If you would like to share your family's story, please call **1-844-606-3339** or email ShareYourStory@hpgroupllc.com

 **KYMRIAHA**[®]
(tisagenlecleucel) Suspension
for IV infusion

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[®] after a bone marrow transplant?
- 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?



Important Safety Information (continued)

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

- 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[®] use in pregnant or breastfeeding women. Therefore, KYMRIA[®] 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.

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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?

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.

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?



Summary of Important Safety Information

What is KYMRIA®?

KYMRIA® (tisagenlecleucel) is made from your own white blood cells and is a prescription cancer treatment used in patients with large B-cell lymphoma, a type of non-Hodgkin lymphoma, that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least two other kinds of treatment.

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

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

• Neurological Toxicities:

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

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 are other serious side effects of KYMRIA®?

• 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. 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 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 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, 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 cancer

Summary of Important Safety Information (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

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

The most common side effects of KYMRIA include:

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

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

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

- 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 use in pregnant or breastfeeding women. Therefore, KYMRIA 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®?

- 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.





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

- ✓ KYMRIAH® (tisagenlecleucel) is a type of immunotherapy called CAR-T cell therapy that uses the power of your own T cells to fight your cancer
- ✓ KYMRIAH is for patients with DLBCL, a type of non-Hodgkin lymphoma, that has relapsed or is refractory after having at least two other kinds of treatment
- ✓ KYMRIAH is given as a single infusion that aims to put your cancer into long-term remission. Your doctor can help you find a KYMRIAH treatment center if you aren't already at one
- ✓ Some patients may experience serious side effects after getting KYMRIAH. Contact your treatment team immediately to help you manage symptoms

Approved Use

What is KYMRIAH?

KYMRIAH is made from your own white blood cells and is a prescription cancer treatment used in patients with large B-cell lymphoma, a type of non-Hodgkin lymphoma, that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least two other kinds of treatment.

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

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

