

I AM KYMRIAH

Tori: actual KYMRIAH CAR-T patient

A Caregiver's Guide to KYMRIAH Therapy

What is KYMRIAH?

KYMRIAH® (tisagenlecleucel) is a prescription cancer treatment used in patients up to 25 years old 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). KYMRIAH is made from your own white blood cells.

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
- fever (100.4°F/38°C or higher)
- chills/shaking chills
- severe nausea, vomiting, diarrhea
- severe muscle or joint pain
- very low blood pressure
- dizziness/lightheadedness

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

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

An innovative kind of treatment

Finding out that your child’s 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 child’s next steps.

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

Read on to learn more about KYMRIAH® (tisagenlecleucel).



Children with cancer may have questions about their condition and treatment. **KYMRIAH FOR KIDS** is a way to explain KYMRIAH to young children. Each section of this brochure includes a question a child might have, and a simple answer. If you are caring for a young child with cancer, look for **KYMRIAH FOR KIDS** throughout the brochure for ways to talk with your child about KYMRIAH.

IMPORTANT SAFETY INFORMATION (continued)

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

Call your health care provider or get emergency help right away if you get any of the following signs and symptoms of:

• Neurological Toxicities:

- altered or decreased consciousness
- delirium
- confusion
- agitation
- seizures
- difficulty speaking and understanding
- loss of balance

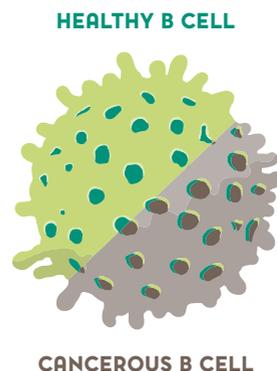
Please see additional Important Safety Information throughout and Summary of Important Information on pages 22 and 23.

What can you find in this brochure?

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- What is KYMRIAH? **5**
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What is B-cell ALL?

B cells are defenders of the body. Along with other cells, they make up the 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).



What does *relapsed or refractory* mean?

It means that your cancer is tough, and other treatments haven't been able to beat it. KYMRIA is a treatment for kids like you who have had other treatments that have not been able to beat their cancer.

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 CRS. If you are admitted to the hospital, tell the health care provider that you have received KYMRIA.

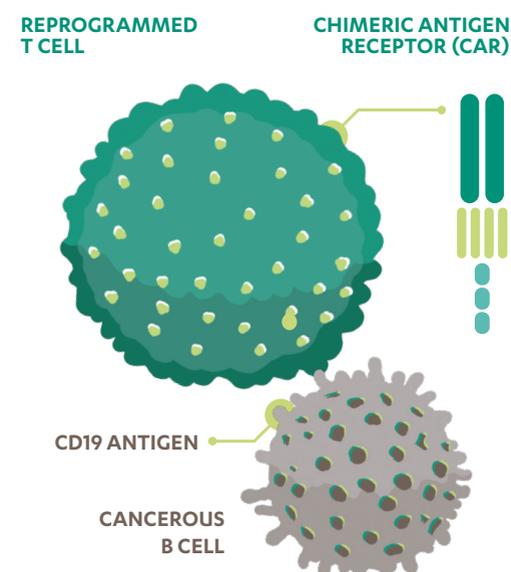
Because of the risk of CRS, and neurological toxicities, KYMRIA is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIA REMS.

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

What is KYMRIA?

KYMRIA is a type of cutting-edge immunotherapy that uses the power of your child's own immune system to treat their 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 child's T cells to detect and destroy their B cells



- The 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 the immune system identify normal cells from infected or cancerous cells; however, cancerous B cells look like normal B cells, so T cells don't always recognize them
- KYMRIA reprograms your child's own T cells into CAR-T cells, which allows them to recognize the CD19 antigen on the surface of their B cells. Your child's new CAR-T cells can destroy the cancerous and other B cells they could not find before

Because KYMRIA uses your child's own T cells, you may hear it referred to as an "individualized" therapy. After being treated with KYMRIA, your child may not need any other treatment for their cancer, though they will continue to be closely monitored by their doctor.

KYMRIA[®]
(tisagenlecleucel) Suspension
for IV infusion

Is KYMRIA[®] right for your child?

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

Talk with your child's doctor about KYMRIA[®]

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

Topics to discuss with your child's doctor:

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



IMPORTANT SAFETY INFORMATION (continued)

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

- **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.

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

What makes KYMRIA[®] different from other therapies?



KYMRIA[®] is different from other cancer therapies because it is an **individualized therapy made just for your child**. KYMRIA[®] is a CAR-T therapy that uses the power of your child's own immune system to fight their cancer.

- Even if your child isn't in remission, they can start KYMRIA[®] therapy
- KYMRIA[®] is typically given in a single infusion, unlike other treatments delivered more than once
- KYMRIA[®] uses a short course of chemotherapy to prepare your child's body for infusion
- Because KYMRIA[®] uses your child's own cells, they do not need a donor

Please see page 12 of this brochure for more information about the side effects of KYMRIA[®].



How does KYMRIA[®] work?

KYMRIA[®] is a special kind of medicine that trains some of your cells to be cancer-fighting cells. KYMRIA[®] is not like other medicines you may have tried because it uses your own body's strength to fight your cancer.

 **KYMRIA[®]**
(tisagenlecleucel) Suspension
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How well does KYMRIA[®] work?

KYMRIA[®] (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 KYMRIA[®], not all patients will respond the same way.

The goal of KYMRIA[®] therapy is long-term remission of your child's cancer

MONTH 3

MORE THAN **8** OUT OF **10**

patients treated with KYMRIA[®] went into remission

Nearly 100% of the patients who went into remission after KYMRIA[®] treatment had no detectable signs of cancer

IMPORTANT SAFETY INFORMATION (continued)

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

- **Prolonged Low Blood Cell Counts (Cytopenia):** KYMRIA[®] can lower one 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, 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 virus vaccine.

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

What are the long-term results?

Since KYMRIA[®] 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 KYMRIA[®].

MONTH 6

75% chance of still being in remission

89% chance of still being alive

MONTH 24

62% chance of still being in remission

66% chance of still being alive

At 24 months, almost 9 out of 10 patients had not gone on to receive a stem cell transplant.

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

What is the process for getting KYMRIAHA?



- 1 Collection**

First, the doctor takes some of your child's blood to collect their 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 child's collected T cells will be reprogrammed into KYMRIAHA® (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 child's treatment team can help guide you and your child through the process.



How do I get KYMRIAHA?

You may go see a different doctor who will take some of your cells from your blood and teach them how to look for your cancer cells. Once your cells know how to find your cancer cells, they will be put back into your body to start fighting your cancer.

- 3 Infusion**

About 2 to 14 days before your child's CAR-T cells are ready, your child will receive a short course of chemotherapy over 4 days that helps prepare your child's body to receive their reprogrammed KYMRIAHA CAR-T cells.

Once your child's treatment team decides they are ready, they will receive their 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 they received their infusion in an inpatient or outpatient setting, it will be necessary to stay close to the hospital for at least 4 weeks after receiving KYMRIAHA.

In the long term, your child's 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 KYMRIAHA be followed for 15 years after infusion. Your child's treatment team will offer their 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 child's treatment team will be there to help guide you through the process.

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 leukemia.
- **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.

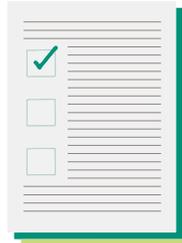


What side effects may your child experience with KYMRIAHA?

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

Get help immediately if they 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 child's immune system becomes highly active. It is the most common and expected side effect of KYMRIAHA, 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. Their treatment team will check their progress after infusion. Members of your child's team are trained to recognize the symptoms of CRS and have specific medicines to treat it.

Neurological Events

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

Prolonged Low Blood Cell Counts (Cytopenia)

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

Low Antibody Levels (Hypogammaglobulinemia)

Because KYMRIAHA CAR-T cells are designed to detect and destroy their B cells, they will also attack the normal B cells in their body. B cells defend your child's body by producing antibodies. Antibodies bind to invaders so other immune cells can destroy them.

After KYMRIAHA, your child may have fewer normal B cells and, therefore, fewer antibodies. A low level of antibodies in their 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 child's risk for infections. Their 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 child's doctor right away if your child develops signs or symptoms of an infection.

Effects on Ability to Drive and Use Machines

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

Most Common Side Effects of KYMRIAHA 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 KYMRIAHA treatment.

Talk to your child's 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** for more information or to submit a report.

What is the KYMRIAH 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 KYMRIAH® (tisagenlecleucel). KYMRIAH is only available through select treatment centers participating in the KYMRIAH REMS Program.

The KYMRIAH REMS Program Patient Wallet Card

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



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

IMPORTANT SAFETY INFORMATION (continued)

What are the most common side effects of KYMRIAH?

Some of the most common side effects of KYMRIAH 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 KYMRIAH. Talk to your health care provider for medical advice about side effects.

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

What kind of support is available?

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



KYMRIAH  CARES®

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

Support comes in many forms

No matter how positive or strong your child is, cancer treatment can be stressful for everyone involved. It is important to seek care for not only your child's physical health, but also their 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 your child, yourself, and those close to you
- 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 child's cancer differently
- Remember to care for your own health and wellness. Take time to exercise, meet a friend for coffee, or see a movie

"The more you know, the more you can help your child, and the more empowered you'll feel."

- Dana, mom of Tori (actual KYMRIAH CAR-T patient)

 **KYMRIAH®**
(tisagenlecleucel) Suspension
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How do you learn more about KYMRIAH?

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

To learn more, visit KYMRIAH.com for educational materials and frequently asked questions. This site also offers an interactive map to help you find certified treatment centers in the United States.

Share your KYMRIAH story

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

Go to KYMRIAH.com to watch other families talk about their experiences with KYMRIAH.



Nick:
actual KYMRIAH CAR-T patient

Like us on Facebook

Explore our Facebook page at 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?

- Your health care provider may do a pregnancy test prior to you starting treatment. There is no information 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.

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Additional support resources



Alex's Lemonade Stand | www.AlexsLemonade.org

Alex's Lemonade Stand Foundation aims to change the lives of children with cancer by funding impactful research, raising awareness, and supporting families.

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.

B+ Foundation | www.BePositive.org

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

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.

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.

Friends of Cancer Research | www.FOCR.org

Friends of Cancer Research drives collaboration among health care stakeholders to deliver life-saving treatments to cancer patients.

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.

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.

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(tisagenlecleucel) Suspension
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What should you ask your child's treatment team?

It is important to know who is on your child's 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 child's medical team during each step of your KYMRIA[®] treatment process.

Initial Discussion

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



Ask your child's 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 child's 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 or cells for transplantation

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.

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

Collection

- How should I prepare my child for collection?
- How long will it take?
- What can my child do during collection?
- Will there be any limitations or side effects afterward?
- How soon after collection will my child's KYMRIA[®] CAR-T cells be ready for infusion?

Preinfusion Lymphodepleting Chemotherapy

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

Infusion

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

Side Effects and Monitoring

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

Renewed hope

There is new hope in a different treatment option for your child's relapsed or refractory B-cell ALL. An option that uses their inner strength. The treatment for your child's cancer may be inside their own cells.

"To see patients go from leaving the hospital and starting to recover, to basically going to school, playing soccer, and looking like every other kid is just wonderful. I think it's the best thing about doing what we do."

- Stephan Grupp, MD, PhD, Oncologist

IMPORTANT SAFETY INFORMATION (continued)

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

KYMRIA[®] (tisagenlecleucel) 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
- fever (100.4°F/38°C or higher)
- chills/shaking chills
- severe nausea, vomiting, diarrhea
- severe muscle or joint pain
- very low blood pressure
- dizziness/lightheadedness

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Glossary

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



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

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

B cells: Along with other cells, they make up the 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 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 therapy that targets certain cells of the immune system to help the body fight cancer, infection, and other diseases.

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

Leukapheresis: When your child's doctor takes some of their blood to collect their T cells.

Refractory: Your child's cancer did not respond to treatment.

Relapsed: Your child's cancer has returned.

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

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

Summary of Important Information

What is KYMRIA®?

KYMRIA® (tisagenlecleucel) is a prescription cancer treatment used in patients up to 25 years old 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). KYMRIA is made from your own white blood cells.

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:

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- fever (100.4°F/38°C or higher)
- chills/shaking chills
- severe nausea, vomiting, diarrhea
- severe muscle or joint pain
- very low blood pressure
- dizziness/lightheadedness

• Neurological Toxicities:

- altered or decreased consciousness
- delirium
- confusion
- agitation
- seizures
- difficulty speaking and understanding
- loss of balance

You may be admitted to the hospital, and treated with other medications, if you have CRS. 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?

- **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 (Cytopenia):** KYMRIA can lower one 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, or have unusual bruising or bleeding.

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 virus 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.
- **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 are the most common side effects of KYMRIA?

Some of the most common side effects of KYMRIA 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 KYMRIA. Talk to your health care provider for medical advice about side effects.

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

- Your health care provider may do a pregnancy test prior to you starting treatment. There is no information 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 or cells for transplantation

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.

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).



I AM KYMRIAH

LJ: actual KYMRIAH CAR-T patient

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



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

