



I  
AM  
KYMRIAH

**Tori:** actual KYMRIAH CAR-T patient

## A Caregiver's Guide to KYMRIAH Therapy

### 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
- 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 Safety 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.

# What can you find in this brochure?

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**Important Safety Information** (continued)

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

- **Neurological Toxicities:**
- Altered or decreased consciousness

◦ Confusion

◦ Difficulty speaking and understanding

◦ Delirium

◦ Agitation

◦ Loss of balance

◦ Seizures

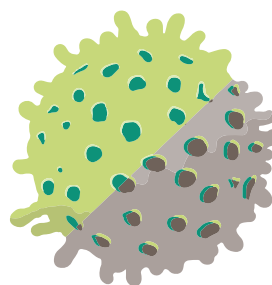
**Please see additional Important Safety Information throughout and Summary of Important Safety Information on pages 22 and 23.**



## 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.

HEALTHY B CELL



CANCEROUS B CELL

## 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<sup>®</sup> (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 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.

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

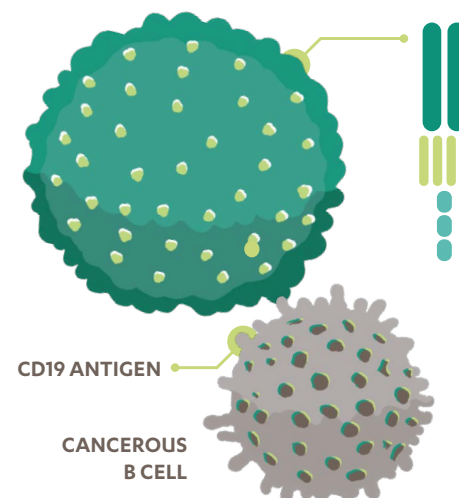
## What is KYMRIA?

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

REPROGRAMMED T CELL

CHIMERIC ANTIGEN RECEPTOR (CAR)



- 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<sup>®</sup>**  
(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?

- **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

## 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.

# 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 child's cancer

MONTH 3

MORE THAN 8 OUT OF 10

patients treated with KYMRIAHA went into remission

Nearly 100% of the patients who went into remission after KYMRIAHA treatment had no detectable signs of cancer

## 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
- **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, 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

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

# 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.

MONTH 6

MONTH 24



chance of still being in remission



chance of still being in remission



chance of still being alive



chance of still being alive

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





# What is the process for getting KYMRIA®?



## 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 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 child's treatment team can help guide you and your child through the process.



### How do I get KYMRIA®?

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 KYMRIA 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 KYMRIA.

**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 KYMRIA 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 KYMRIA®? (continued)

- **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 side effects may your child experience with KYMRIA®?

KYMRIA® (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 KYMRIA.

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 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. 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

KYMRIA 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.

### 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 they have low levels of 1 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 KYMRIA. 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 KYMRIA 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 KYMRIA, 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 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 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.**

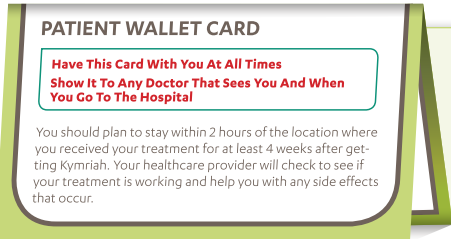
**Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

# 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 child's completed wallet card with you at all times.



Visit [www.KYMRIA-REMS.com](http://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 are the possible or reasonably likely side effects of KYMRIA?

The most common side effects of KYMRIA include:

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

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

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

# What kind of support is available?

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



KYMRIA CARES®

Please call **1-844-4KYMRIA (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 KYMRIA CAR-T patient)

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



# 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](https://www.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](mailto:ShareYourStory@inspired-patients.com).

Go to [KYMRIAH.com](https://www.kymriah.com) to watch other 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

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

# Additional support resources



### Alex’s Lemonade Stand | [www.AlexsLemonade.org](https://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](https://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](https://www.BePositive.org)

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

### CancerCare | [www.CancerCare.org](https://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](https://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](https://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](https://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](https://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](https://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](https://www.StBaldricks.org)

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

### Stupid Cancer | [www.StupidCancer.org](https://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 you ask your child's treatment team?

It is important to know who is on your child's KYMRIA<sup>®</sup> (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<sup>®</sup> treatment process.

## Initial Discussion

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



### Ask your child's doctor for a KYMRIA<sup>®</sup> 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<sup>®</sup>?

- 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<sup>®</sup>. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIA<sup>®</sup> can be found at [www.KYMRIA.com](http://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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Please see additional Important Safety Information throughout and Summary of Important Safety 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<sup>®</sup> 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<sup>®</sup> 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

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

# 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 Safety Information

## What is KYMRIA®?

KYMRIA® (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?

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
  - 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 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
- **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
  - 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?

- 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](http://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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**





A portrait of a young boy with light brown, wavy hair and black-rimmed glasses. He is looking directly at the camera with a neutral expression. He is wearing a dark blue button-down shirt. The background is a plain, light gray.

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



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