Adult Relapsed/Refractory Diffuse Large B-cell Lymphoma Robyn and Nick: actual KYMRIAH CAR-T patients

> Pediatric and Young Adult Relapsed/Refractory Acute Lymphoblastic Leukemia

Discuss KYMRIAH With Your Doctor

Approved Uses

What is KYMRIAH?

KYMRIAH 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). It is also used in patients with large B-cell lymphoma, a type of non-Hodgkin lymphoma, that has relapsed or is refractory 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
- Fever (100.4°F/38°C or higher)
- Chills/shaking chills
- Neurological Toxicities:
- Altered or decreased consciousness
 Delirium
- Severe nausea, vomiting, diarrhea
- Severe muscle or joint pain
- ∘ Confusion
- Agitation
- Seizures

Difficulty speaking and

• Very low blood pressure

Dizziness/lightheadedness

- understanding
- Loss of balance



<u>Please see additional Important Safety Information throughout and</u> <u>on pages 4 and 5</u> and <u>full Prescribing Information, including Boxed</u> <u>WARNING, and Medication Guide</u>.

What should I ask my treatment team?

KYMRIAH® (tisagenlecleucel) is an individualized treatment made just for you. Since KYMRIAH is different from other therapies, you may be unsure of the process. Your treatment team is here to answer any questions you may have. Refer to this list to help guide your discussions about each step of the KYMRIAH treatment process, from initial discussion to monitoring.

Notes:



Initial Discussion

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

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 KYMRIAH CAR-T cells be ready for infusion?

It is important to know who is on your KYMRIAH treatment team and how to get in touch with them. Ask your doctor for a **KYMRIAH Patient Binder** to help you keep track of important information such as appointments, business cards, emergency numbers, email addresses, and notes from your discussions with your medical team.

Important Safety Information (continued)

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

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Preinfusion Lymphodepleting Chemotherapy

How is this chemotherapy different from the chemotherapy I previously received?

Notes:

- How long will it take?
- Will there be side effects?
- How far in advance of my infusion do I receive chemotherapy?

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

Infusion



Side Effects and Monitoring

- What precautions do I need to take after treatment?
- What side effects should I expect after infusion?
- How will serious side effects be managed after therapy?
- How will I know KYMRIAH® (tisagenlecleucel) is working?
- What will be my monitoring plan after treatment?
- 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?

Important Safety Information (continued)

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

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

What are other serious side effects of KYMRIAH?

• 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

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

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

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

What are other serious side effects of KYMRIAH?

- 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 KYMRIAH. 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: KYMRIAH 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):** KYMRIAH 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 KYMRIAH, and you may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with KYMRIAH. Tell your health care provider about your treatment with KYMRIAH before receiving a live vaccine
- Secondary Cancers: KYMRIAH may increase your risk of getting cancers, including certain types of blood cancers. Your health care provider should monitor you for this
- 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



Important Safety Information (continued)

How will I get KYMRIAH?

- Since KYMRIAH 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 KYMRIAH. 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
- 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

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

The most common side effects of KYMRIAH include:

• Difficulty breathing

• Severe muscle or joint pain

• Fever (100.4°F/38°C or higher)

Very low blood pressureDizziness/lightheadedness

Chills/shaking chills

Confusion

- Headache
- Severe nausea, vomiting, diarrhea

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

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

What should I be aware of after receiving KYMRIAH?

- 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 KYMRIAH. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIAH can be found at www.KYMRIAH.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 <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

<u>Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for additional information.</u>





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