

I AM KYMRIAH

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® (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). 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
- 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

Please see additional Important Safety Information throughout and Summary of Important Safety Information on pages 4 and 5.

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

Summary of Important Safety Information

What is KYMRIA[®]?

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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

Summary of Important Safety Information (continued)

How will I get KYMRIAHI?

- Since KYMRIAHI® (tisagenlecleucel) 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 KYMRIAHI. 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 KYMRIAHI to be made, your health care provider may give you therapy to stabilize your cancer
- In addition, before you get KYMRIAHI, 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 KYMRIAHI 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 KYMRIAHI. 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 KYMRIAHI?

The most common side effects of KYMRIAHI 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 KYMRIAHI. Talk to your health care provider for medical advice about side effects.

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

- 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 KYMRIAHI use in pregnant or breastfeeding women. Therefore, KYMRIAHI 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 KYMRIAHI?

- 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 KYMRIAHI. Talk with your health care provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for KYMRIAHI can be found at www.KYMRIAHI.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.