



Child portrayed is not a real KYMRIAH patient.

DISCUSSION GUIDE

What should I ask my treatment team?

Making treatment decisions for relapsed or refractory cancer can be hard. Asking questions along the way can help make things easier. Be sure to talk with your treatment team about any questions or concerns you may have about KYMRIAH™ (tisagenlecleucel). Refer to this list at any step of the process to help guide your discussions and use the space available to take notes.

IMPORTANT INFORMATION

What is KYMRIAH?

KYMRIAH 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 refractory (did not go into remission with other leukemia treatments). KYMRIAH is made from your own white blood cells.

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 4 to 5.

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 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:

- 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 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.
- **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.



Summary of Important Information (continued)

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

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).

