

For adults with follicular lymphoma that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least 2 other kinds of treatment

# BREAKFREE FROM THE CYCLE

A SINGLE INFUSION. A CHANCE AT LASTING REMISSION.

#### What is KYMRIAH® (tisagenlecleucel)?

KYMRIAH is made from your own white blood cells and is a prescription cancer treatment used in patients with follicular lymphoma (FL), a type of non-Hodgkin lymphoma, that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least two other kinds of treatment.

There are ongoing studies to confirm the benefit of KYMRIAH in FL.

(tisagenlecleucel) Suspension for IV infusion

# KYMRIAH OFFERS A CHANCE AT LASTING REMISSION



KYMRIAH enhances the ability of your T cells to detect and destroy your healthy and cancerous B cells



KYMRIAH is typically given in a single infusion made up of your own immune cells



Collaboration with your treatment team and caregivers is imperative

Making treatment decisions for relapsed or refractory follicular lymphoma can be challenging. Talk with your treatment team about questions you may have.

Visit KYMRIAH.com to learn more about KYMRIAH, treatment centers, and available support

#### 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

# WHAT IS RELAPSED/REFRACTORY FOLLICULAR LYMPHOMA?

The immune system is made up of different cells and organs that work together to protect the body from diseases. For example, there are B cells, T cells, and glands called lymph nodes. Sometimes the cells inside a lymph node can grow abnormally and become cancerous.

Follicular lymphoma is a type of non-Hodgkin lymphoma (cancer of the immune system) that develops from B cells and is usually slow growing.

When your cancer is in **remission**, it means the signs and symptoms of cancer have decreased or disappeared. Your cancer is considered to have **relapsed** when it comes back after a period of remission, and to be **refractory** when it does not respond to treatment.



#### T cells

T cells are a key part of your immune system that can find and destroy cells that are infected or that have become cancerous.



#### B cells

B cells are also a key component of your immune system. They make special proteins called antibodies, which attach to the surface of foreign invaders, alerting your body to the presence of intruders. Some B cells can then remember the intruders so if they see them again in the future, they can respond more quickly.



#### Cancerous cells

Your healthy B cells can sometimes change and develop into a cancer, including DLBCL. These abnormal B cells continue to grow and increase in number, which can affect your body in different ways.

#### **IMPORTANT SAFETY INFORMATION (cont)**

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

- Neurological Toxicities:
  - · Altered or decreased consciousness
  - Delirium
  - Confusion
  - Agitation

- Seizures
- Difficulty speaking and understanding
- Loss of balance

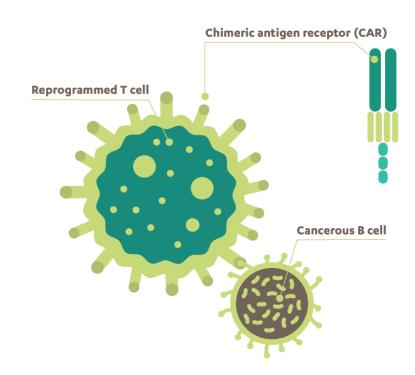


# KYMRIAH IS A SINGLE INFUSION MADE FROM YOUR OWN IMMUNE CELLS

Unlike traditional chemotherapy or stem cell transplant, KYMRIAH is a type of immunotherapy, called CAR-T cell therapy or chimeric antigen receptor T cell therapy. KYMRIAH is made up of your own T cells that have been reprogrammed to recognize the antigen CD19, allowing them to better detect and destroy cancerous (and normal) B cells in the body.

KYMRIAH is approved in patients with follicular lymphoma that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least 2 other kinds of treatment.

KYMRIAH is a **single infusion** that may allow patients to break free from the cycle of daily oral medications and multiple intravenous infusions.



#### **IMPORTANT SAFETY INFORMATION (cont)**

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

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.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 13-15.

# WHAT IS THE PROCESS FOR GETTING KYMRIAH?\*

#### **Collecting your T cells**



Your T cells will be collected via blood through a process called leukapheresis (loo-kuh-fuh-REE-sis), where your white blood cells are removed from your blood. This process typically takes 3 to 6 hours



# **KYMRIAH CAR-T** cell manufacturing **Preparing for your infusion**

Your collected T cells will be reprogrammed into CAR-T cells at a specialized manufacturing facility. The process usually takes **3 to 4 weeks**, but timing and manufacturing outcomes can vary



#### Infusing your CAR-T cells

Once your treatment team decides you are ready, you will receive your CAR-T cells through a single infusion that takes **less than 30 minutes**. Before your infusion, your physician will decide if you need a short course of chemotherapy to help prepare your body for CAR-T cells



#### **Short-term monitoring**

Regular monitoring to manage side effects is important. Whether you received your infusion in an inpatient or outpatient setting, it will be necessary to stay close to your treatment center for at least 4 weeks after receiving KYMRIAH

#### Long-term monitoring

Your 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 KYMRIAH be followed for 15 years after infusion. Your treatment team will offer you 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



<sup>\*</sup>KYMRIAH is only available at select treatment centers.

# KYMRIAH IS A POTENTIALLY DEFINITIVE, SINGLE INFUSION THAT MAY BREAK THE CYCLE OF REPEATED TREATMENTS IN ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA

In a global, phase 2 pivotal study (ELARA), **82**% of patients did not require another anti-lymphoma treatment within 12 months post infusion



**Multiple IV Infusions** 



**Daily Oral Medications** 



**Indefinite Repeated Treatment Cycles** 

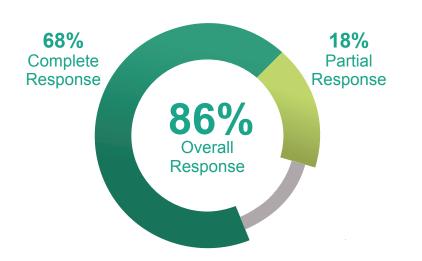
#### **IMPORTANT SAFETY INFORMATION (cont)**

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

# **NEARLY 90% OF PATIENTS RESPONDED TO TREATMENT WITH KYMRIAH**

In the phase 2 ELARA clinical trial, KYMRIAH delivered strong efficacy in adult patients





18%

(16 of 90) of patients achieved a **partial response** 

 18% of adults have shown a decrease in cancer cells within the body

#### **IMPORTANT SAFETY INFORMATION (cont)**

What are other serious side effects of KYMRIAH? (cont)

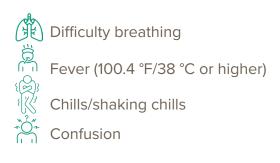
- Prolonged Low Blood Cell Counts (Cytopenias): KYMRIAH can lower 1 or more types of your blood cells (red blood cells, white blood cells, or platelets). After treatment, your health care provider may test your blood to check cell counts. Tell your health care provider right away if you get a fever or 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

Please see additional Important Safety Information throughout and Summary of Important Information on pages 13-15.

# WHAT SIDE EFFECTS MAY I EXPERIENCE?

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

Call your health care provider or seek emergency help right away if you experience any of the following:





Dizziness/lightheadedness



Loss of balance





Difficulty speaking and understanding

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 cytokine release syndrome and neurological toxicities, KYMRIAH is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.

#### **IMPORTANT SAFETY INFORMATION (cont)**

What are other serious side effects of KYMRIAH? (cont)

- Secondary Cancers: After treatment with KYMRIAH, 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 KYMRIAH because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures

# 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 completed wallet card with you at all times.

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

#### **IMPORTANT SAFETY INFORMATION (cont)**

#### 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 SHOULD I ASK MY TREATMENT TEAM?

Knowing who is on your treatment team for KYMRIAH and how to get in touch with them are important. Remember to ask for names, telephone numbers, email addresses, and any other contact information.

Initial questions might include the following:

- How does my treatment history affect my eligibility for KYMRIAH?
- Can I receive KYMRIAH after a bone marrow transplant?
- 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?

Click **here** for a discussion guide to use with your doctor.



#### **IMPORTANT SAFETY INFORMATION (cont)**

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

- · 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

# WHAT SHOULD I ASK MY TREATMENT TEAM?

#### Collection

- How should I prepare for the 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?

#### **Preinfusion Lymphodepleting Chemotherapy**

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

#### Infusion

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

#### **Side Effects and Monitoring**

- What side effects should I expect after infusion?
- How will serious side effects be managed after therapy?
- How will I know KYMRIAH is working?
- 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 (cont)**

#### 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



# AS A CAREGIVER, HOW I CAN HELP THROUGHOUT THE PROCESS?

Finding out your loved one's cancer has returned or hasn't responded to treatment can be hard on everyone's mental and emotional well-being. It is important to tap into available resources and practice self-care during this difficult time. Leaning on social and emotional support networks, engaging in physical activity, and connecting with spirituality can be helpful.

You can help by watching for side effects. KYMRIAH can be given in an inpatient (stay in the center) or outpatient (leave center after infusion) setting. Before leaving the treatment center, your treatment team will give you a list of potential side effects to watch for, as well as instructions for what to do if they happen.

KYMRIAH is only available at select treatment centers. These centers have been specially certified in how to manage the risks of cytokine release syndrome and neurological toxicities. Therefore, it will be necessary to stay close to your treatment center for at least 4 weeks after receiving KYMRIAH.



#### **IMPORTANT SAFETY INFORMATION (cont)**

#### 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 <a href="https://www.KYMRIAH.com">www.KYMRIAH.com</a>, 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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 13-15.

# SUMMARY OF IMPORTANT SAFETY INFORMATION

#### What is KYMRIAH?

KYMRIAH is made from your own white blood cells and is a prescription cancer treatment used in patients with follicular lymphoma (FL), a type of non-Hodgkin lymphoma, that has relapsed (went into remission, then came back) or is refractory (did not go into remission after receiving other lymphoma treatments) after having at least two other kinds of treatment.

There are ongoing studies to confirm the benefit of KYMRIAH in FL.

#### 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

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.



# **SUMMARY OF IMPORTANT SAFETY INFORMATION (continued)**

#### 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: After treatment with KYMRIAH, 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 KYMRIAH because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures

#### 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

# **SUMMARY OF IMPORTANT SAFETY INFORMATION (continued)**

- 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
- 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.

#### 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 <a href="https://www.KYMRIAH.com">www.KYMRIAH.com</a>, 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.



# WHAT KIND OF SUPPORT IS AVAILABLE?

American Cancer Society www.Cancer.org

CancerCare www.CancerCare.org

Cancer Research Institute www.CancerResearch.org

Friends of Cancer Research www.FOCR.org

Leukemia & Lymphoma Society www.LLS.org

Lymphoma Research Foundation www.Lymphoma.org

Patient Advocate Foundation www.PatientAdvocate.org

Cancer Support Community www.CancerSupportCommunity.org

The 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 on these websites. The organizations listed on this page do not specifically endorse the use of KYMRIAH.

For information about financial assistance, patient support programs, or finding a treatment center, contact



To learn more, please call KYMRIAH CARES™ at (1-844-459-6742) from 8:00 AM to 8:00 PM ET.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 13-15.



**Novartis Pharmaceuticals Corporation** East Hanover, New Jersey 07936-1080