CARVYKTI® (ciltacabtagene autoleucel) is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least one other treatment has not worked or has stopped working. CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells.

In the fight against relapsed or refractory multiple myeloma

DON'T WAIT TO FIND OUT IF CARVYKTI® MAY BE RIGHT FOR YOU

Ask your doctor about CARVYKTI®, a CAR-T treatment that ignites your own body's defense to fight cancer



#### **IMPORTANT SAFETY INFORMATION**

# What is the most important information I should know about CARVYKTI®?

CARVYKTI® may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing

- very low blood pressure
- dizziness/lightheadedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
- feeling confused, less alert, or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing, and understanding words, memory loss
- o loss of coordination affecting movement and

- balance, slower movements, changes in handwriting
- personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
- tingling, numbness, and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
- facial numbness, difficulty moving muscles of face and eyes

Please read full <u>Important Safety Information</u>.

Please read full <u>Prescribing Information</u>, including <u>Boxed Warning</u>, and read the <u>Medication Guide</u>. Discuss any questions you have with your healthcare team.



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#### **IMPORTANT SAFETY INFORMATION**

It is important that you tell your healthcare providers that you have received CARVYKTI® and to show them your CARVYKTI® Patient Wallet Card. Your healthcare providers may give you other medicines to treat your side effects.



#### WHO IS CARVYKTI® FOR?

If you're considering CARVYKTI®, you've already been treated with at least one treatment regimen that contains a **proteasome inhibitor**, and an **immunomodulatory agent**, and you have not responded to or stopped responding to **lenalidomide**.

In addition, your multiple myeloma (MM) has either returned or has stopped responding to treatment, and your doctor has determined that it's time to take the next appropriate step to help you manage this illness.

GLOSSARY >

Throughout this brochure, you'll see certain **bold typeface** words and phrases. That means you can find a definition of each bolded term in the Glossary on pages 23-24.

#### **IMPORTANT SAFETY INFORMATION**

Before you receive CARVYKTI® tell your healthcare provider about all your medical conditions, including if you have:

- Current or past neurologic problems (such as seizures, stroke, new or worsening memory loss)
- Lung or breathing problems
- Heart problems

- Liver problems
- Kidney problems
- A recent or active infection
- Low blood counts



#### WHY CONSIDER A CAR-T CELL THERAPY LIKE CARVYKTI®?



#### What is CARVYKTI®?

CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells.

#### Why would I consider CARVYKTI® CAR-T cell therapy?

If your RRMM has stopped responding to lenalidomide and you have had a proteasome inhibitor and an immunomodulatory agent, talk to your healthcare provider about whether CARVYKTI® may be an appropriate next step for you.

CAR-T=chimeric antigen receptor-T cell; FDA=U.S. Food and Drug Administration; RRMM=relapsed/refractory multiple myeloma.

GLOSSARY >

#### **IMPORTANT SAFETY INFORMATION**

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### How will I receive CARVYKTI®?

- CARVYKTI® is made from your own white blood cells, so your blood will be collected by a process called 'leukapheresis' (loo-kah-furee-sis). The procedure can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are sent to a manufacturing center to make CARVYKTI®.
- It takes about 4-5 weeks from the time your cells are received at the manufacturing site and are available to be shipped back to your healthcare provider, but the time may vary.
- While CARVYKTI® is being made, you may get other medicines to treat the multiple myeloma. This is so that your multiple myeloma does not get worse.



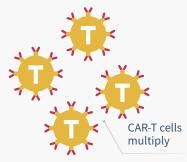
## **HOW CARVYKTI® CAR-T CELL THERAPY WORKS**



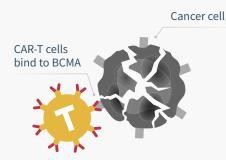
**T cells** are a type of immune cell that patrols the body for signs of infection and disease, and then starts a response to attack them. But sometimes cancer cells are structured in a way that prevents T cells from recognizing or attacking them.



**CAR-T cell therapy** works through collection and genetic modification of your body's own T cells to create personalized **CAR-T cells** that will recognize and fight your cancer. Your CAR-T cells are then returned to your body in a one-time infusion.



CAR-T cells will multiply in your body so that you have even more cells seeking out and destroying cancer cells.



CARVYKTI® CAR-T cells are designed to find and attack **BCMA**, a protein found on the outside of nearly all multiple myeloma cells as well as on normal plasma cells. BCMA is **over-expressed** on multiple myeloma cells.

BCMA=B-cell maturation antigen; CAR-T=chimeric antigen receptor-T cell.

GLOSSARY >

#### **IMPORTANT SAFETY INFORMATION**

Before you get CARVYKTI®, your healthcare provider will give you chemotherapy for 3 days to prepare your body.

30 to 60 minutes before you are given CARVYKTI®, you may be given other medicines. These may include:

- medicines for an allergic reaction (antihistamines)
- medicines for fever (such as acetaminophen)

When your CARVYKTI® is ready, your healthcare provider will give CARVYKTI® to you through a catheter (tube) placed into your vein (intravenous infusion). Your dose of CARVYKTI® will be given in one infusion bag. The infusion usually takes approximately 30-60 minutes.



# CARVYKTI® PATIENTS LIVED LONGER WITHOUT THEIR DISEASE PROGRESSING OR PASSING AWAY COMPARED TO THOSE RECEIVING ONE OF TWO STANDARD THERAPY COMBINATIONS

In a clinical study of 419 patients, 208 were treated with CARVYKTI® and 211 were treated with one of two types of standard MM therapy.

CARVYKTI® was compared to patients receiving: daratumamab, pomalidomide, and dexamethasone or bortezomib, pomalidomide, and dexamethasone.

For patients receiving CARVYKTI® there was a 59% reduction of risk of their RRMM getting worse or passing away vs those receiving one of two standard therapy combinations

#### After one year:

**76%** 

Three-quarters of patients (76%) who took CARVYKTI® were living without their disease worsening or passing away

compared to

**50%** 

**Half of patients (50%)** who took one of two standard therapy combinations were living **without** their disease worsening or passing way

MM=multiple myeloma; RRMM=relapsed or refractory multiple myeloma.

#### **IMPORTANT SAFETY INFORMATION**

**After getting CARVYKTI®**, you will be monitored at the certified healthcare facility where you received your treatment for at least 10 days after the infusion.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

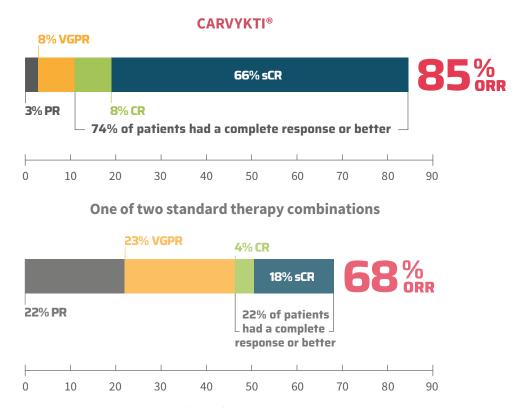
Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.



# **MORE** RRMM PATIENTS RESPONDED TO CARVYKTI<sup>®</sup> COMPARED TO ONE OF TWO STANDARD THERAPY COMBINATIONS

In a clinical study of 419 patients, 208 were treated with CARVYKTI® and 211 were treated with one of two types of standard MM therapy.

CARVYKTI® was compared to patients receiving: daratumamab, pomalidomide, and dexamethasone or bortezomib, pomalidomide, and dexamethasone.



Overall Response Rate (ORR): The percentage of patients who have any kind of response to multiple myeloma treatment.

MM=multiple myeloma; RRMM=relapsed or refractory multiple myeloma.

#### **Types of Treatment Responses**

- Stringent complete response (sCR): the best results of treatment with a drug, in which the doctor is unable to observe any signs or symptoms of the disease through the use of very sensitive techniques, including imaging or other specific tests
- Complete response (CR): when the doctor observed no signs or symptoms of the disease as seen through standard tests, including imaging or other specific blood and bone marrow tests after treatment
- **Very good partial response (VGPR):** a treatment outcome in which there is a greater than 90% decrease in M-protein
- Partial response (PR): when there is a greater than 50% decrease in M-protein and disappearance of some (but not all) signs and symptoms of cancer



# CARVYKTI® PATIENTS HAD A LONGER LASTING RESPONSE COMPARED TO THOSE RECEIVING ONE OF TWO STANDARD THERAPY COMBINATIONS

In a clinical study of 419 patients, 208 were treated with CARVYKTI® and 211 were treated with one of two types of standard MM therapy.

CARVYKTI® was compared to patients receiving: daratumamab, pomalidomide, and dexamethasone or bortezomib, pomalidomide, and dexamethasone.

# Median length of time for a patient to have a first response MONTH for one of two standard therapy combinations MONTH 1 MONTH 2 The median\* length of time to a first response was longer for CARVYKTI® patients (2 months) than patients with one of two standard therapy combinations (1 month).

**Median duration of response** 



At the time of follow-up, patients on the standard therapy reached a median duration of response at 16.6 months.

Because CARVYKTI® patients continued to respond, a median duration of response was not reached.

Duration of response is the length of time patients responded to treatment without their disease progressing.

MM=multiple myeloma.

#### **IMPORTANT SAFETY INFORMATION**

# What should I avoid after receiving CARVYKTI®?

 Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI®. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider.

- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI® treatment. Talk to your healthcare provider if you need to have any vaccinations.
- Do not donate blood, organs, tissues, or cells for transplantation.



<sup>\*</sup>Median is the middle number in a group of numbers arranged from lowest to highest.

#### What is CARVYKTI® (ciltacabtagene autoleucel)?

- CARVYKTI® is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least one other treatment has not worked or has stopped working
- CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells

#### **IMPORTANT SAFETY INFORMATION**

# What is the most important information I should know about CARVYKTI®?

CARVYKTI® may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing
- very low blood pressure
- dizziness/lightheadedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
- feeling confused, less alert, or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing, and understanding words, memory loss
- loss of coordination affecting movement and balance, slower movements, changes in handwriting

- personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
- tingling, numbness, and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
- o facial numbness, difficulty moving muscles of face and eyes It is important that you tell your healthcare providers that you have received CARVYKTI® and to show them your CARVYKTI® Patient Wallet Card. Your healthcare providers may give you other medicines to treat your side effects.

# Before you receive CARVYKTI® tell your healthcare provider about all your medical conditions, including if you have:

- Current or past neurologic problems (such as seizures, stroke, new or worsening memory loss)
- Lung or breathing problems
- Heart problems
- Liver problems
- Kidney problems
- A recent or active infection
- Low blood counts

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



# **IMPORTANT SAFETY INFORMATION** (more)

#### How will I receive CARVYKTI®?

- CARVYKTI® is made from your own white blood cells, so your blood will be collected by a process called 'leukapheresis' (loo-kah-fur-ee-sis). The procedure can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are sent to a manufacturing center to make CARVYKTI<sup>®</sup>. It takes about 4-5 weeks from the time your cells are received at the manufacturing site and are available to be shipped back to your healthcare provider, but the time may vary.
- While CARVYKTI® is being made, you may get other medicines to treat the multiple myeloma. This is so that your multiple myeloma does not get worse.

Before you get CARVYKTI®, your healthcare provider will give you chemotherapy for 3 days to prepare your body.

30 to 60 minutes before you are given CARVYKTI®, you may be given other medicines. These may include:

- medicines for an allergic reaction (antihistamines)
- medicines for fever (such as acetaminophen)

When your CARVYKTI® is ready, your healthcare provider will give CARVYKTI® to you through a catheter (tube) placed into your vein (intravenous infusion). Your dose of CARVYKTI® will be given in one infusion bag. The infusion usually takes approximately 30-60 minutes.

**After getting CARVYKTI®**, you will be monitored at the Certified Treatment Center where you received your treatment for at least 10 days after the infusion.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

#### What should I avoid after receiving CARVYKTI®?

- Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI®. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider.
- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI® treatment. Talk to your healthcare provider if you need to have any vaccinations.
- Do not donate blood, organs, tissues, or cells for transplantation.



# **IMPORTANT SAFETY INFORMATION** (more)

#### What are the possible or reasonably likely side effects of CARVYKTI®?

The most common side effects of CARVYKTI® include:

- fever (100.4°F/38°C or higher), chills
- dizziness or light-headedness
- headache, muscle or joint pain, feeling very tired
- altered mental state, confusion
- infections
- low levels of antibodies (immunoglobulins) in the blood
- cough, being short of breath
- diarrhea, nausea, decreased appetite, constipation
- fast or irregular heartbeat
- problems with blood clotting

In a study comparing CARVYKTI® to standard therapy, there was a higher rate of death in the first 10 months in the CARVYKTI® arm (14%) compared to the standard therapy arm (12%). The increased rate of deaths occurred before receiving CARVYKTI® and after treatment with CARVYKTI®. The reasons for death were progression of multiple myeloma and side effects of the treatment

CARVYKTI® can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or lightheadedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI®.

CARVYKTI® can increase the risk of life-threatening infections including COVID-19 that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

CARVYKTI® can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements, changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.



# **IMPORTANT SAFETY INFORMATION** (more)

CARVYKTI® can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]), which may make you feel weak or tired, or increase your risk of severe infection or bleeding that may lead to death. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

CARVYKTI® may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

Having CARVYKTI® in your blood may cause some commercial Human Immunodeficiency Virus (HIV) tests to incorrectly give you an HIV-positive result even though you may be HIV-negative.

These are not all the possible side effects of CARVYKTI®. Call your healthcare provider if you have any side effects.

You may report side effects to FDA at 1-800-FDA-1088.

Please read full <u>Prescribing Information</u>, including Boxed Warning, for CARVYKTI®.

cp-258861v6



# CARVYKTI®: A PERSONALIZED MEDICINE DELIVERED THROUGH A ONE-TIME INFUSION

#### Your body's own immune cells are genetically modified to find and fight multiple myeloma cells

As part of the multi-step CARVYKTI® treatment process, your body's own immune cells (T cells) are collected and then genetically modified into personalized CAR-T cells designed to seek out and destroy cancer cells.



For more information on what to expect at each stage of your CARVYKTI® journey, <u>click here</u> to watch the CARVYKTI® Treatment Process video.

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.

CAR-T=chimeric antigen receptor-T cell.

#### **IMPORTANT SAFETY INFORMATION**

In a study comparing CARVYKTI® to standard therapy, there was a higher rate of death in the first 10 months in the CARVYKTI® arm (14%)

compared to the standard therapy arm (12%). The increased rate of deaths occurred before receiving CARVYKTI® and after treatment with CARVYKTI®. The reasons for death were

progression of multiple myeloma and side effects of the treatment.



<sup>\*</sup>Timing and outcomes of manufacturing may vary.

<sup>&</sup>lt;sup>†</sup>208/208 patients in the CARTITUDE-4 study received bridging therapy.

#### THE CARVYKTI® TREATMENT PROCESS

#### **STEP 1 Cell collection**



Some of your blood is drawn into a machine that separates the white and red blood cells, collects some of the white blood cells (including T cells), and returns the rest of the blood into your body. This process is called **leukapheresis** (loo-kuh-fur-ee-sis). This process may take ~3 to 6 hours and may need to be repeated until the process is complete.

#### **STEP 2 Genetically modifying your T cells**



Your white blood cells are frozen and sent to a manufacturing site, where the T cells are separated out and customized into your CARVYKTI® CAR-T cells. This is done by genetically modifying your T cells to be able to recognize BCMA on the surface of multiple myeloma cells. Your CARVYKTI® CAR-T cells are then frozen and sent to your CARVYKTI® Certified Treatment Center.

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.

BCMA=B cell maturation antigen; CAR-T=chimeric antigen receptor-T cell.

\*Timing and outcomes of manufacturing may vary.

<sup>†</sup>208/208 patients in the CARTITUDE-4 study received bridging therapy.

#### **IMPORTANT SAFETY INFORMATION**

#### What are the possible or reasonably likely side effects of CARVYKTI®?

The most common side effects of CARVYKTI® include:

- fever (100.4°F/38°C or higher), chills
- dizziness or light-headedness
- headache, muscle or joint pain, feeling very tired

#### **TIPS FOR CARE PARTNERS**

Continue to support the person you care for while their CAR-T cells are being manufactured, and remember that their healthcare provider is there to help every step of the way. Communicate frequently with both the person you care for and their healthcare provider, and do not hesitate to ask questions as needed.



# THE CARVYKTI® TREATMENT PROCESS (more)

#### **STEP 3 Pre-infusion treatment**



A few days before your infusion of CARVYKTI®, you'll receive low-dose chemotherapy infusions with cyclophosphamide and fludarabine.

These infusions will help prepare your body for the CAR-T infusion. Each of these infusions will be given to you once a day

for 3 days. These infusions are given to help clear out some of your white blood cells to make the necessary space in your immune system for CARVYKTI®. This is also known as **lymphodepleting chemotherapy**.

CAR-T=chimeric antigen receptor-T cell.

\*208/208 patients in the CARTITUDE-4 study received bridging therapy.

#### **STEP 4 One-time CARVYKTI® infusion**



About a month after your initial cell collection, and 2 to 4 days after your last low-dose chemotherapy, you'll be given your CARVYKTI® through a one-time intravenous infusion that takes approximately 30 to 60 minutes. Your healthcare provider will guide you through what your infusion day will be like.

Between cell collection and pre-infusion treatment, your doctor may prescribe additional therapy to treat your multiple myeloma, often called bridging therapy.\*

#### **IMPORTANT SAFETY INFORMATION**

What are the possible or reasonably likely side effects of CARVYKTI®? (more)

- altered mental state, confusion
- infections
- low levels of antibodies (immunoglobulins) in the blood

- · cough, being short of breath
- diarrhea, nausea, decreased appetite, constipation
- fast or irregular heartbeat
- problems with blood clotting

CARVYKTI® can cause a very common side effect called cytokine release syndrome or CRS,

which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or lightheadedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI®.



# THE CARVYKTI® TREATMENT PROCESS (more)

#### **STEP 5 Monitoring**



After your infusion of CARVYKTI®, your healthcare provider at the CARVYKTI® Certified Treatment Center will closely monitor you daily for 10 days following infusion for any signs or symptoms of a reaction to treatment.

You should plan to stay close to the location

where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to

#### **TIPS FOR CARE PARTNERS**

You are an extra set of eyes and ears for the healthcare provider—you can alert them quickly if any side effects occur. Be observant, and be prepared by keeping the names and phone numbers of the members of the healthcare team nearby.

reschedule. After this 4-week monitoring period, your healthcare provider will continue to provide care and partner with you to create a plan for long-term monitoring and regular follow-ups. Let your healthcare provider know if you're not feeling well. **Refrain from driving or hazardous activities for at least 8 weeks following treatment with CARVYKTI**®.

#### **IMPORTANT SAFETY INFORMATION**

CARVYKTI® can increase the risk of lifethreatening infections including COVID-19 that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection. CARVYKTI® can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements,

changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.



#### RECOGNIZING SYMPTOMS OF POTENTIAL SIDE EFFECTS

CARVYKTI® may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider right away if you are experiencing or if you think you are experiencing any symptoms of the side effects listed in the Important Safety Information.

#### The CARVYKTI® REMS Program

What is the CARVYKTI® REMS Program? A Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program that the U.S. Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies and healthcare professionals must take extra steps to make sure the benefits of using the drug are greater than the risks. The FDA must approve these steps as part of a REMS program.

Due to the risk of serious side effects such as **cytokine release syndrome (CRS)** and **neurotoxicity**, which can be life-threatening and can lead to death, CARVYKTI® can be administered only at healthcare settings certified in the CARVYKTI® REMS Program.

As part of the CARVYKTI® REMS Program, you will be given a CARVYKTI® Patient Wallet Card either before or at the time of receiving your CARVYKTI® infusion. Work with your healthcare providers to fill out the card, and be sure to carry your completed CARVYKTI® Patient Wallet Card with you at all times. For more information about the CARVYKTI® REMS Program or to download a replacement card if needed, visit www.CARVYKTIrems.com

#### **IMPORTANT SAFETY INFORMATION**

CARVYKTI® can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]), which may make you feel weak or tired, or increase

your risk of severe infection or bleeding that may lead to death. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

CARVYKTI® may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.



#### SUPPORT THROUGH YOUR TREATMENT EXPERIENCE

#### Why is self-care important?

Taking care of yourself can feel like a big task, but the most important person in your treatment journey is you: Your experiences and feelings matter.

Being diagnosed with RRMM can trigger many confusing thoughts and emotions. This diagnosis can lead to a list of overwhelming responsibilities like appointments, tests, and medical decisions. It's important to leverage the resources around you to help support you throughout your treatment journey.

#### **Tapping into resources and support**



There are helpful resources available for you and your Care Partners, including support programs, education materials, and Certified Treatment Center locations. For more information about these resources and how they may be able to help, <u>click here</u>.

#### Tracking your experience



Using a journal to keep track of your feelings each day can help you see how your experiences might be changing. Journaling can also remind you of questions to ask your doctor, helping your doctor and medical team better understand your treatment journey. For more information and support on tracking your treatment journey, <u>click here</u> to explore the CARVYKTI® Patient Milestone Guidebook.

#### **Speaking up**



Sometimes when we don't feel well, we don't feel like talking to others. However, it's very important to communicate often with your Care Partners, family, friends, and medical team. Your thoughts and ideas matter, and it's important to express them.

RRMM=relapsed/refractory multiple myeloma.

#### **IMPORTANT SAFETY INFORMATION**

Having CARVYKTI® in your blood may cause some commercial Human Immunodeficiency Virus (HIV) tests to incorrectly give you an HIV- positive result even though you may be HIV-negative.

These are not all the possible side effects of CARVYKTI®. Call your healthcare provider if you have any side effects.

You may report side effects to FDA at 1-800-FDA-1088.



#### TIPS FOR CARE PARTNERS



Your role in supporting the person you care for the encouragement, emotional support, and practical assistance you provide—makes you an important part of the treatment experience. You may need to help the person you care for with:

- Monitoring and tracking signs and symptoms of side effects
- Scheduling appointments
- Providing transportation to appointments and keeping them company
- Helping communicate with the healthcare provider (for example, providing medical and insurance information, asking questions)
- Responsibilities at home
- Emotional support and having someone to talk with
- Managing their schedule and letting visitors know when they do or don't feel up to seeing them

You don't have to manage this alone. Support is available to help you along the way, and you may want to identify friends or family who can help you as well.



For additional information, <u>click here</u> to view all the CARVYKTI® partner resource materials.



# **MyCARVYKTI® PATIENT SUPPORT PROGRAM**

Traveling away from home for medical care can be financially and logistically challenging. Support is available for eligible patients and their Care Partners.

The MyCARVYKTI® Patient Support Program, sponsored by Janssen Biotech, Inc., and Legend Biotech, is designed to help eligible patients prescribed CARVYKTI® and their Care Partners with support during treatment.

Patients who meet financial and other eligibility requirements, and their Care Partners, may receive:



Assistance with transportation, lodging, and out-of-pocket costs related to meals and other travel expenses associated with treatment at the CARVYKTI® Certified Treatment Center



Support from MyCARVYKTI® Patient Support Specialists, who are available to help guide you through the enrollment process and assist with program benefits





## **QUESTIONS TO ASK YOUR HEALTHCARE PROVIDER**

While going through the treatment process, it is important to remember that your healthcare provider is there to assist you. If you have any questions about your treatment, do not hesitate to ask a member of the CARVYKTI® Certified Treatment Center staff.

Below are examples of questions you may want to ask your healthcare provider at the Certified Treatment Center.

#### **Patient**

"How will my doctor help determine whether CARVYKTI® is right for me?"

"When am I eligible for CARVYKTI®?"

"Where do I stay while going through the process?"

"How long will this evaluation/procedure take?"

"When I'm receiving treatment with CARVYKTI® at a Certified Treatment Center, will I be able to get up and move around?"

"What results should I expect?"

"What side effects can I expect, and how long will they last?"

"What support services are available to me?"

#### **Care Partner**

"What is my role/responsibility throughout the treatment process?"

"Who do I contact if I have questions/concerns?"

"Will I be allowed access to the person I care for and their healthcare provider on a regular basis?"

"Where can I find information to help me understand the treatment process and resources?"

"What symptoms of the potential side effects should I look for?"



#### **TIPS FOR CARE PARTNERS**

Be an advocate for the person you care for—if they or you have questions about any aspect of treatment, ask a member of the Certified Treatment Center staff. They expect you to have lots of questions, and they understand that providing answers to your questions is an important part of a successful treatment experience.



## **GLOSSARY**

Below you will find definitions for terms related to CAR-T cell therapy with CARVYKTI® that may be unfamiliar to you.

**B-cell maturation antigen (BCMA)**—a kind of marker that is found on the surface of myeloma cells and some types of immune cells.

**CAR-T cells**—T cells that have been genetically modified in a laboratory to effectively identify targets on cancer cells in order to bind to and destroy them.

**CAR-T cell therapy**—a cancer treatment in which your T cells are collected and then genetically modified to create customized CAR-T cells that will fight your cancer. These CAR-T cells are then returned to your body in a one-time infusion.

**Complete response (CR)**—when the doctor observed no signs or symptoms of the disease as seen through standard tests, including imaging or other specific blood and bone marrow tests after treatment.

**Cytokine release syndrome (CRS)**—a condition that can occur after some types of immunotherapy treatment such as treatment with monoclonal and CAR-T cell infusions. CRS is caused by the rapid release of cytokines into the blood from immune cells affected by the immunotherapy. Cytokines are immune substances that have many different purposes in the body. Most patients have a mild reaction, but sometimes the reaction may be severe or life-threatening.

**Duration of response (DoR)**—the length of time patients responded to treatment without their disease progressing.

**Immunomodulatory agent**—a chemical agent that modifies the immune response or the functioning of the immune system.

**Lenalidomide**—a type of chemotherapy cancer treatment that may help the immune system kill cancer cells and may also prevent the growth of new blood vessels that allow tumors to grow.

**Leukapheresis**—the first step of the CARVYKTI® treatment process. In this step, your blood is drawn and passed through a machine that collects some of your blood, separates out some of your white blood cells, and then returns the rest of the blood to your body. This process takes approximately 3 to 6 hours. The collected T cells are then sent to a manufacturing lab where they will be used to make your unique CAR-T cells.

**Lymphodepleting chemotherapy**—a step in the CARVYKTI® treatment process that takes place a few days before your infusion. To prepare your body to receive CARVYKTI®, you are given infusions of low-dose chemotherapy once a day for 3 consecutive days. This treatment reduces the number of white blood cells in your body, giving the CARVYKTI® CAR-T cells room to multiply once they are returned to your body.

**M-protein**—The monoclonal protein secreted by cancerous myeloma cells.

**Median**—the middle number in a group of numbers arranged from lowest to highest.

**Neurotoxicity**—occurs when the exposure to toxic substances alters the normal activity of the nervous system. This can eventually disrupt neurons (key cells that transmit and process signals in the brain and other parts of the nervous system). Neurologic toxicity can result from exposure to substances used in chemotherapy, radiation treatment, drug therapies, and organ transplants, or exposure to other substances. Individuals with certain disorders may be especially vulnerable to substances that can cause neurologic toxicity.

CAR-T=chimeric antigen receptor-T cell.



## **GLOSSARY** (more)

Below you will find definitions for terms related to CAR-T cell therapy with CARVYKTI® that may be unfamiliar to you.

**Overall response rate (ORR)**— is a measurement made during or after treatment that measures how many patients in a clinical study respond to a specific therapy.

**Over-expressed**—when a marker or protein expressed by several types of cells is more highly expressed by one type of cell. For example, B cell maturation antigen (BCMA) is overexpressed on myeloma cells compared with healthy plasma cells.

**Partial response (PR)**—when there is a greater than 50% decrease in M-protein and disappearance of some (but not all) signs and symptoms of cancer.

**Proteasome inhibitors and immunomodulatory agents**—two different forms of treatment for multiple myeloma that patients receive prior to being eligible for CAR-T cell therapy with CARVYKTI®.

Proteasome inhibitors include Immunomodulatory agents include

Bortezomib Lenalidomide
Carfilzomib Thalidomide
Ixazomib Pomalidomide

**Stringent complete response (sCR)**—the best results of treatment with a drug, in which the doctor is unable to observe any signs or symptoms of the disease through the use of very sensitive techniques, including imaging or other specific tests.

**T cells**—a type of immune cell that patrols the body for signs of infection and diseases, and initiates a response to attack both.

**Very good partial response (VGPR)**—a treatment outcome in which there is a greater than 90% decrease in M-protein.

CAR-T=chimeric antigen receptor-T cell.





# Scan the code to visit **CARVYKTI.com** to learn more

Please read full <u>Important Safety Information</u>.

Please read full <u>Prescribing Information</u>, including Boxed Warning, and read the <u>Medication Guide</u>. Discuss any questions you have with your healthcare team.

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