CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

In relapsed or refractory multiple myeloma (RRMM)

CARVYKTI®: A ONE-TIME INFUSION WITH DEEP AND DURABLE RESPONSE[1-3]

The 28-month median follow-up analysis showed

98%
OVERALL RESPONSE RATE
(95/97, 95% CI: 92.7-99.7)[1]

80%
STRINGENT COMPLETE RESPONSE
(78/97, 95% CI: 71.1-87.8)[1*]

95%
ACHIEVED DEEP RESPONSES[†]
(92/97)[1]

NOT ESTIMABLE
MEDIAN DURATION OF RESPONSE
(95% CI: 23.3-NE)[1]

Review longer-term 5-year data on the pages ahead

CD38=cluster of differentiation 38; CI=confidence interval; NE=not estimable.
*All complete responses were stringent complete responses.[1]
[†]Deep response is defined as Very Good Partial Response or Better (≥VGPR).[1]

INDICATIONS AND USAGE

CARVYKTI® (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.

STUDY DESIGN[1,2]

CARTITUDE-1 was a phase 1b/2 open-label, multicenter study evaluating the efficacy and safety of a single infusion of CARVYKTI® in adult patients with relapsed or refractory multiple myeloma who had previously received at least 3 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

In total, 97 patients were treated with CARVYKTI®; all were evaluable for efficacy. Primary endpoint in phase 1b was safety. Primary efficacy endpoint in phase 2 was overall response rate; selected secondary endpoints included the rate of stringent complete response, very good partial response, duration of response, and safety.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED and RECURRENT CYTOPENIA, and SECONDARY HEMATOLOGICAL MALIGNANCIES

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome (GBS) and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®.

Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment with CARVYKTI®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®.

Please see the full Important Safety Information throughout and on pages 10-13, and read accompanying full Prescribing Information, including Boxed Warning, for CARVYKTI®.

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CARTITUDE-1 STUDY

PHASE 1b/2, OPEN-LABEL, MULTICENTER TRIAL EVALUATING SAFETY, OVERALL RESPONSE, AND DURABILITY IN 97 ADULT PATIENTS WITH RRMM[1,2*]

Primary objectives[1,3,4]

PHASE 1b:

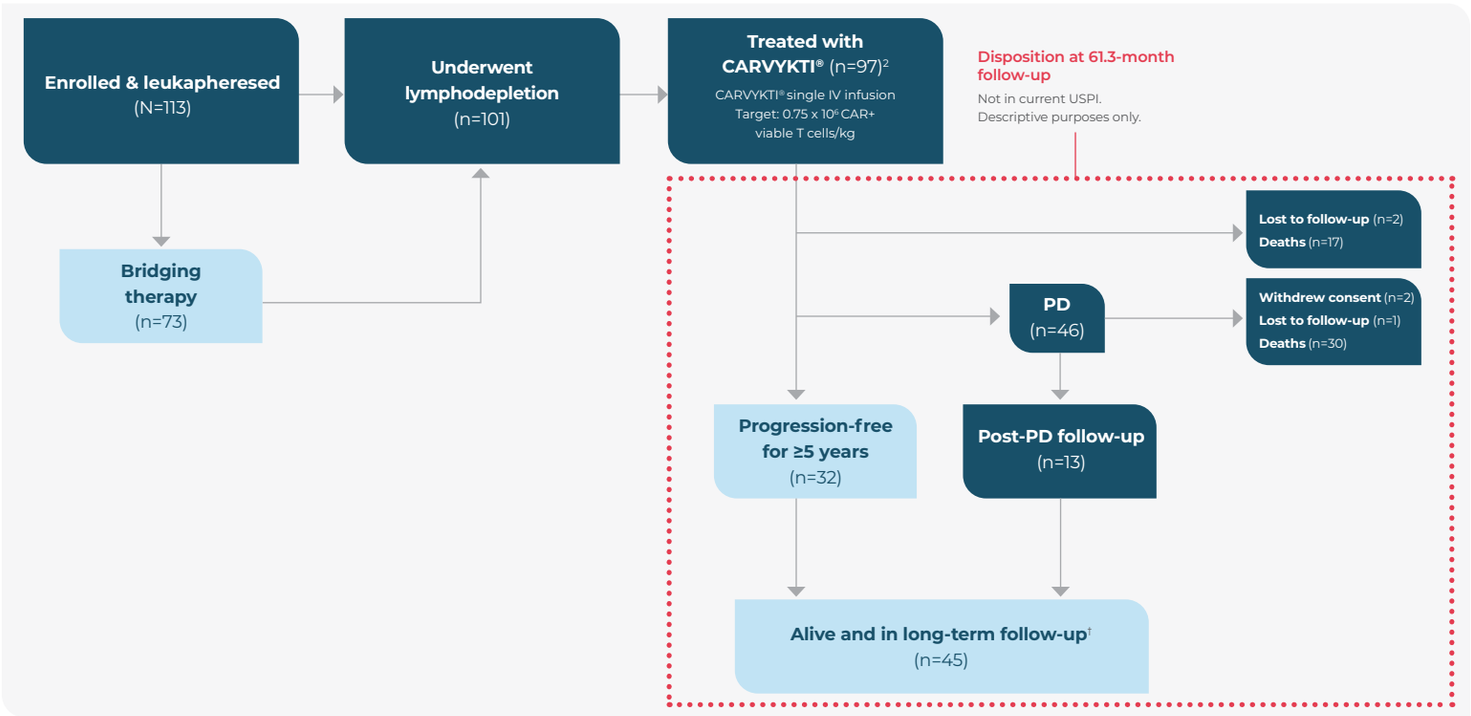
Characterize safety and confirm phase 2 dose

PHASE 2:

Evaluate efficacy:

- ORR (primary endpoint)
- sCR, CR, VGPR, DOR, TTR, PFS, OS (select secondary endpoints)

- The median time from leukapheresis to product availability was 32 days (range, 27-66 days)[1]
- Of the 97 patients, 17 patients (18%) received CARVYKTI® with manufacturing failures either because the product did not meet product release specifications or there were insufficient data to confirm the product release specifications for CARVYKTI®[1]



CAR=chimeric antigen receptor; CR=complete response; DOR=duration of response; IV=intravenous; ORR=overall response rate; OS=overall survival; PD=progressive disease; PFS=progression-free survival; RRMM=relapsed or refractory multiple myeloma; sCR=stringent complete response; TTR=time to response; VGPR=very good partial response.

*See key eligibility criteria.

†At median 61.3-month follow-up.[3]

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.

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CARTITUDE-1 EVALUATED PATIENTS WITH HEAVILY PRETREATED RRMM

Key inclusion criteria[1,2]

- Diagnosis of MM per IMWG criteria, with measurable disease
- ≥3 previous LoT (or double refractory to a PI and an immunomodulatory agent)
- Previous treatment with a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- Disease progression per IMWG criteria within 12 months of last LoT
- ECOG PS grade of 0-1*

Exclusion criteria[1,2]

- Prior treatment with CAR-T directed at any target
- Prior therapy that is targeted to BCMA
- Known active or prior history of significant CNS disease, including CNS multiple myeloma
- Plasma cell leukemia
- Allogeneic stem cell transplant within 6 months before apheresis or ongoing treatment with immunosuppressants
- Creatinine clearance <40 mL/min
- Absolute lymphocyte concentration <300/µL
- Absolute neutrophil count <750 cells/mm^2
- Platelet count <50,000/mm^2
- Hepatic transaminases >3x the upper limit of normal
- Cardiac ejection fraction <45%
- Active serious infection

BCMA=B-cell maturation antigen; CAR-T=chimeric antigen receptor-T cell; CD38=cluster of differentiation 38; CNS=central nervous system; ECOG PS=Eastern Cooperative Oncology Group performance status; IMWG=International Myeloma Working Group; LoT=line(s) of therapy; PI=proteasome inhibitor.
*ECOG performance status at baseline was 2 in 4% of patients.[2]

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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CARTITUDE-1 STUDY

CARTITUDE-1 STUDY: SELECT BASELINE CHARACTERISTICS (N=97)[1,2]

DEMOGRAPHICS	
Age, range (median)	43-78 years (61)
Male (n)	59% (57)
African American (n)	18% (17)
ECOG performance status 0 (n)	40% (39)
ECOG performance status 1 (n)	56% (54)
ECOG performance status 2 (n)	4% (4)

DISEASE	
High-risk cytogenetic profile (n)*	24% (23)
Extramedullary plasmacytomas ≥1 (n)	13% (13)†
Tumor BCMA expression ≥50% (n)	92% (57)‡
CrCl <45 mL/min (n)	3% (3)

PRIOR TREATMENTS	
Time since diagnosis, median	5.9 years
Prior lines of therapy, median (range)	6 (3-18)
Triple-class exposed (n)§	100% (97)
Penta-exposed (n)‖	84% (81)
Triple-class refractory (n)§	88% (85)
Penta-refractory (n)‖	42% (41)
Refractory to last line of therapy (n)¶	99% (96)
Previous autologous stem cell transplant (n)	90% (87)
Previous allogeneic stem cell transplant (n)	8% (8)

BCMA=B-cell maturation antigen; CD38=cluster of differentiation 38; CrCl=creatinine clearance; del=deletion; ECOG=Eastern Cooperative Oncology Group.
*Based on the presence of del(17p), t(14;16), or t(4;14).[1,2]
†Additional 6 patients had a soft-tissue component of a bone-based plasmacytoma (total plasmacytomas, 19.6%).[5]
‡Denominator n=62, the number of evaluable samples; BCMA expression detected in all evaluable samples.[5]
§≥1 proteasome inhibitor, ≥1 immunomodulatory agent, and 1 anti-CD38 monoclonal antibody.[2]
‖≥2 proteasome inhibitors, ≥2 immunomodulatory agents, and 1 anti-CD38 monoclonal antibody.[2]
¶Two patients were refractory to other anti-CD38 antibodies.[2]

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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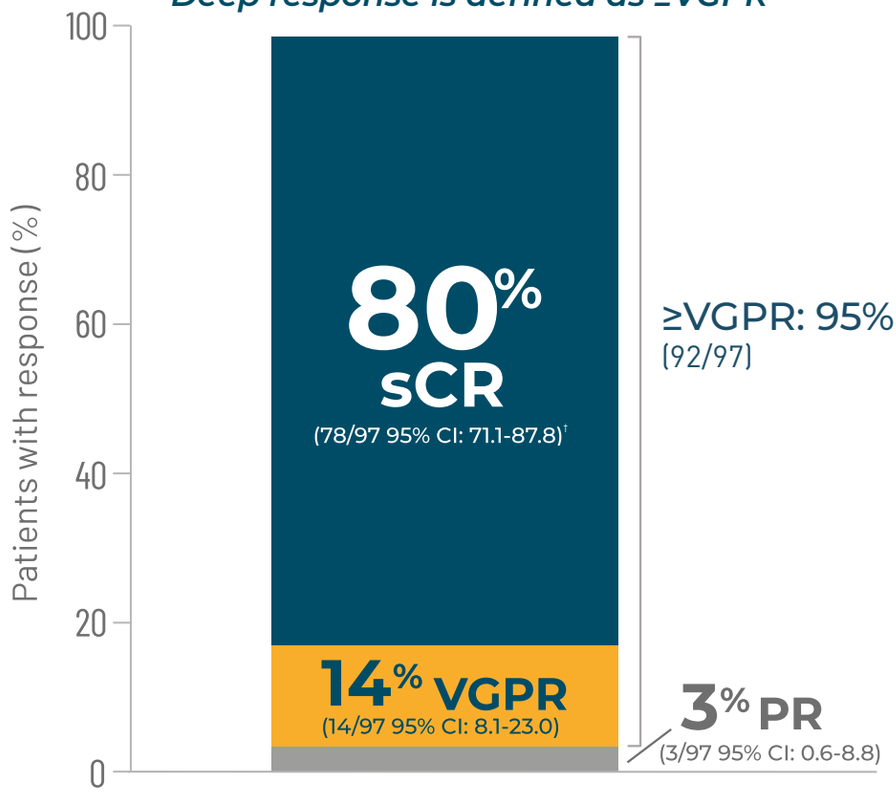
MEDIAN FOLLOW-UP: 28 MONTHS

95% OF PATIENTS ACHIEVED DEEP RESPONSES WITH CARVYKTI®[1,3]

In CARTITUDE-1

98%
ORR
(95/97 95% CI: 92.7-99.7)

Deep response is defined as ≥VGPR



RESPONSES WERE DURABLE THROUGH 28 MONTHS OF FOLLOW-UP[1,2]*

mDOR NOT ESTIMABLE
(95% CI: 23.3-NE)[1,2]

CI=confidence interval; mDOR=median duration of response; NE=not estimable; ORR=overall response rate; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.
*Based on a median duration of follow-up of 28 months.[1]
†All complete responses were sCRs.[1]

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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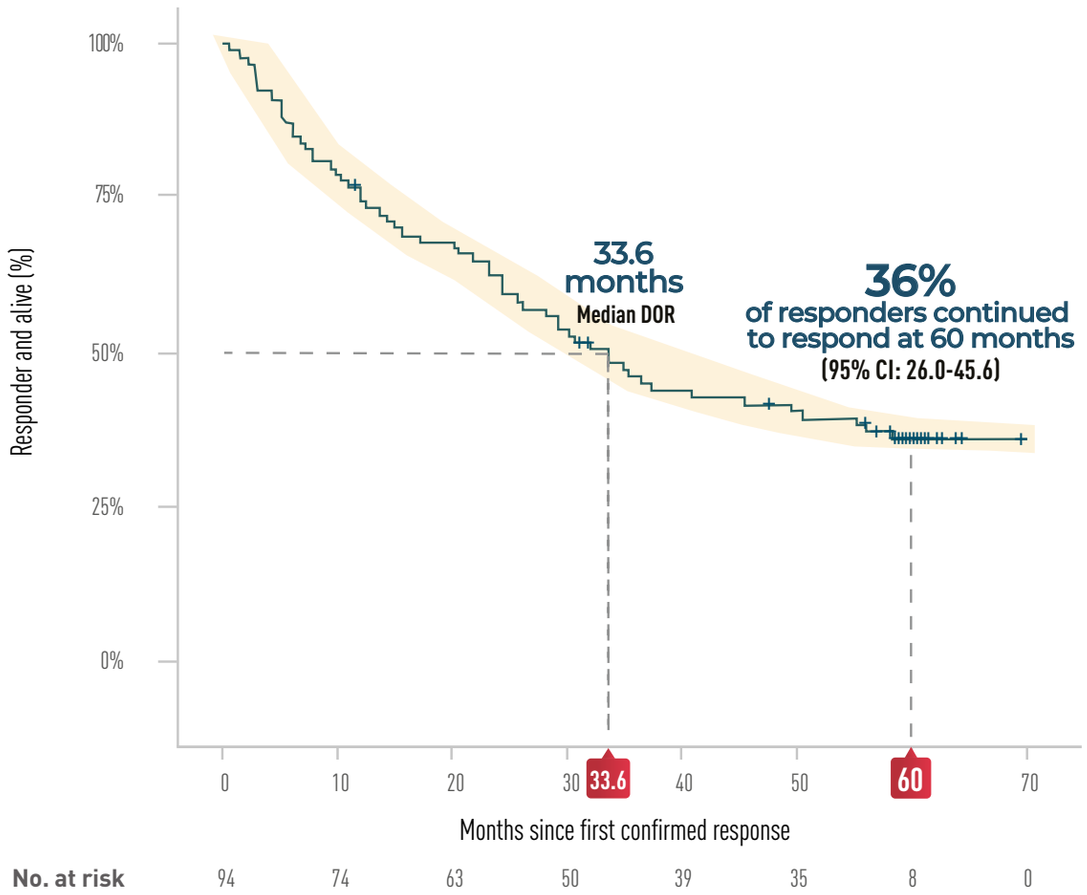
36% OF RESPONDERS CONTINUED TO RESPOND AT 60 MONTHS

You are now viewing an analysis from the CARTITUDE-1 trial with a median duration follow-up of 61.3 months. This information is not included in the current USPI and should be interpreted with caution.

Duration of response in CARVYKTI® responders (n=94)[6*†]



- At data cut-off (median follow-up of 61.3 months), **46%** of patients (45/97) were alive and in long-term follow-up

CI=confidence interval; DOR=duration of response; USPI=United States Prescribing Information.
Percentage rounded to nearest whole number.
*Responders defined as having partial response or better as determined by investigator.
†Median follow-up was 61.3 months in the All-Treated Analysis Set. Response and disease progression assessed by investigator.[6]

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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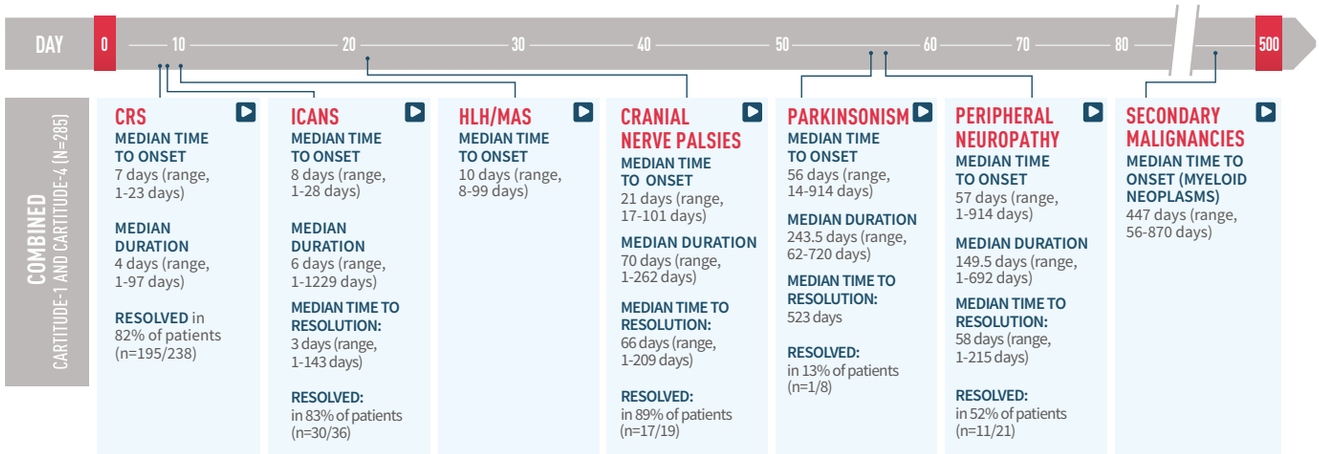
CARVYKTI® HAS A WELL-STUDIED SAFETY PROFILE ACROSS MULTIPLE TRIALS[1]



		CRS	ICANS	CRANIAL NERVE PALSIES	PARKINSONISM	PERIPHERAL NEUROPATHY
CARTITUDE-4 INCIDENCE	Any grade	78%	7%	9%	1%	7%
	Grade ≥3	3%	0.5%	1%	0%	0.5%

		CRS	ICANS	CRANIAL NERVE PALSIES	PARKINSONISM	PERIPHERAL NEUROPATHY
CARTITUDE-1 INCIDENCE	Any grade	95%	23%	3%	6%	7%
	Grade ≥3	4%	3%	1%	4%	2%

No new cases of Parkinsonism or cranial nerve palsies were reported in CARTITUDE-1 from the 27.7-month follow-up (above) up to the 61.3-month follow-up.[3,7]
Information is not included in the current USPI.

INCREASED EARLY MORTALITY
Inform patients of the risk of early mortality, which has occurred prior to or after infusion. In CARTITUDE-4, a randomized (1:1), controlled trial, there was a numerically higher percentage of early deaths in patients randomized to the CARVYKTI® treatment arm (29/208; 14%) compared with the control arm (25/211; 12%) within the first 10 months from randomization.

CARTITUDE-4 is a phase 3, randomized, open-label, multicenter controlled study in adult patients with relapsed and lenalidomide-refractory multiple myeloma, who previously received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent. A total of 419 patients were randomized 1:1 to receive either a sequence of apheresis, bridging therapy, lymphodepletion, and CARVYKTI® (n=208) or standard therapy which included daratumumab, pomalidomide, and dexamethasone (DPd) or bortezomib, pomalidomide, and dexamethasone (PVd) selected by physician prior to randomization based on patient's prior antimyeloma therapy (n=211).

CRS=cytokine release syndrome; HLH=hemophagocytic lymphohistiocytosis; ICANS=immune effector cell-associated neurotoxicity syndrome; MAS=macrophage activation syndrome; USPI=United States Prescribing Information.

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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ADVERSE REACTIONS ≥10%

IN CARTITUDE-1[1]

ADVERSE REACTIONS OBSERVED IN ≥10% OF PATIENTS TREATED WITH CARVYKTI® IN CARTITUDE-1 (N=97)

System Organ Class (SOC) Preferred Term	Any Grade (%)	Grade 3 or Higher (%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		
Coagulopathy*	22	2
Febrile neutropenia	10	9
CARDIAC DISORDERS		
Tachycardia†	27	1
GASTROINTESTINAL DISORDERS		
Diarrhea‡	33	1
Nausea	31	1
Constipation	22	0
Vomiting	20	0
GENERAL DISORDERS AND ADMINISTRATIVE SITE CONDITIONS		
Pyrexia	96	5
Fatigue†	47	7
Chills	33	0
Edema§	23	0
IMMUNE SYSTEM DISORDERS		
Cytokine release syndrome†	95	5
Hypogammaglobulinemia‖	93	2
INFECTIONS AND INFESTATIONS		
Infections-pathogen unspecified†	41	19
Upper respiratory tract infection†	28	3
Viral infections†	23	7
Pneumonia†	14	13
Sepsis†	10	7

IgG=immunoglobulin G.
*Coagulopathy includes Activated partial thromboplastin time prolonged, Coagulopathy, Disseminated intravascular coagulation, Hypofibrinogenemia, International normalized ratio increased, and Prothrombin time prolonged.
†Represents multiple related terms.
‡Diarrhea includes Colitis and Diarrhea.
§Edema includes Face edema, Generalized edema, Localized edema, Edema peripheral, Periorbital edema, Peripheral swelling, Pulmonary edema, and Scrotal edema.
‖Hypogammaglobulinemia includes subjects with adverse event of hypogammaglobulinemia and/or laboratory IgG levels that fell below 500 mg/dL following CARVYKTI® infusion.

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.

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ADVERSE REACTIONS ≥10% (cont)

IN CARTITUDE-1[1]

ADVERSE REACTIONS OBSERVED IN ≥10% OF PATIENTS TREATED WITH CARVYKTI® IN CARTITUDE-1 (N=97)

System Organ Class (SOC) Preferred Term	Any Grade (%)	Grade 3 or Higher (%)
METABOLISM AND NUTRITION DISORDERS		
Decreased appetite	29	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Musculoskeletal pain*	48	2
NERVOUS SYSTEM DISORDERS		
Encephalopathy†	30	6
Headache	27	0
Dizziness*	23	1
Motor dysfunction‡	16	3
PSYCHIATRIC DISORDERS		
Insomnia	13	0
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS		
Cough*	39	0
Dyspnea§	23	3
Nasal congestion	15	0
Hypoxia	12	4
NEOPLASMS: BENIGN, MALIGNANT, AND UNSPECIFIED (INCLUDING CYSTS AND POLYPS)		
Hematologic malignancy‖	10	10
VASCULAR DISORDERS		
Hypotension*	51	10
Hypertension	19	6
Hemorrhage¶	16	4

*Represents multiple related terms.
†Encephalopathy includes Amnesia, Bradyphrenia, Confusional state, Depressed level of consciousness, Disturbance in attention, Encephalopathy, Immune effector cell-associated neurotoxicity syndrome, Lethargy, Memory impairment, Mental impairment, Mental status changes, Noninfective encephalitis, and Somnolence.
‡Motor dysfunction includes Motor dysfunction, Muscle spasms, Muscle tightness, Muscular weakness, and Myoclonus.
§Dyspnea includes Acute respiratory failure, Dyspnea, Dyspnea exertional, Respiratory failure, and Tachypnea.
‖Hematologic malignancy includes Myelodysplastic syndrome and Acute myeloid leukemia.
¶Hemorrhage includes Conjunctival hemorrhage, Contusion, Ecchymosis, Epistaxis, Eye contusion, Hematochezia, Hemoptysis, Infusion site hematoma, Oral contusion, Petechiae, Post procedural hemorrhage, Pulmonary hemorrhage, Retinal hemorrhage, and Subdural hematoma.

SELECTED IMPORTANT SAFETY INFORMATION

Fatal or life-threatening reactions occurred in patients following treatment with CARVYKTI®, including Cytokine Release Syndrome (CRS), Parkinsonism, and Guillain-Barré syndrome, and their associated complications, and Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS). HLH/MAS can occur with CRS or neurologic toxicities. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which can be fatal or life-threatening, occurred after treatment, before CRS onset, concurrently with CRS, after CRS resolution, or in absence of CRS. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery, and secondary hematological malignancies, including myelodysplastic syndrome, acute myeloid leukemia, and T-cell malignancies occurred following treatment.
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IMPORTANT SAFETY INFORMATION

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Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome (GBS) and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®.

Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life-threatening reactions, occurred following treatment with CARVYKTI®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®.

WARNINGS AND PRECAUTIONS

Increased early mortality. In CARTITUDE-4, a (1:1) randomized controlled trial, there was a numerically higher percentage of early deaths in patients randomized to the CARVYKTI® treatment arm compared to the control arm. Among patients with deaths occurring within the first 10 months from randomization, a greater proportion (29/208; 14%) occurred in the CARVYKTI® arm compared to (25/211; 12%) in the control arm. Of the 29 deaths that occurred in the CARVYKTI® arm within the first 10 months of randomization, 10 deaths occurred prior to CARVYKTI® infusion, and 19 deaths occurred after CARVYKTI® infusion. Of the 10 deaths that occurred prior to CARVYKTI® infusion, all occurred due to disease progression, and none occurred due to adverse events. Of the 19 deaths that occurred after CARVYKTI® infusion, 3 occurred due to disease progression, and 16 occurred due to adverse events. The most common adverse events were due to infection (n=12).

Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® for RRMM in the CARTITUDE-1 & -4 studies (N=285), CRS occurred in 84% (238/285), including ≥ Grade 3 CRS (ASTCT 2019) in 4% (11/285) of patients. Median time to onset of CRS, any grade, was 7 days (range: 1 to 23 days). CRS resolved in 82% with a median duration of 4 days (range: 1 to 97 days). The most common manifestations of CRS in all patients combined (≥10%) included fever (84%), hypotension (29%) and aspartate aminotransferase increased (11%). Serious events that may be associated with CRS include pyrexia, hemophagocytic lymphohistiocytosis, respiratory failure, disseminated intravascular coagulation, capillary leak syndrome, and supraventricular and ventricular tachycardia. CRS occurred in 78% of patients in CARTITUDE-4 (3% Grade 3 to 4) and in 95% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. HLH/MAS is a potentially life-threatening condition. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Confirm that a minimum of 2 doses of tocilizumab are available prior to infusion of CARVYKTI®.

Of the 285 patients who received CARVYKTI® in clinical trials, 53% (150/285) patients received tocilizumab; 35% (100/285) received a single dose, while 18% (50/285) received more than 1 dose of tocilizumab. Overall, 14% (39/285) of patients received at least 1 dose of corticosteroids for treatment of CRS.

Monitor patients at least daily for 7 days following CARVYKTI® infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 2 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic toxicities, which may be severe, life-threatening, or fatal, occurred following treatment with CARVYKTI®. Neurologic toxicities included ICANS, neurologic toxicity with signs and symptoms of Parkinsonism, GBS, immune mediated myelitis, peripheral neuropathies, and cranial nerve palsies. Counsel patients on the signs and symptoms of these neurologic toxicities, and on the delayed nature of onset of some of these toxicities. Instruct patients to seek immediate medical attention for further assessment and management if signs or symptoms of any of these neurologic toxicities occur at any time.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies for RRMM, one or more neurologic toxicities occurred in 24% (69/285), including ≥ Grade 3 cases in 7% (19/285) of patients. Median time to onset was 10 days (range: 1 to 101) with 63/69 (91%) of cases developing by 30 days. Neurologic toxicities resolved in 72% (50/69) of patients with a median duration to resolution of 23 days (range: 1 to 544). Of patients developing neurotoxicity, 96% (66/69) also developed CRS. Subtypes of neurologic toxicities included ICANS in 13%, peripheral neuropathy in 7%, cranial nerve palsy in 7%, parkinsonism in 3%, and immune mediated myelitis in 0.4% of the patients.

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS): Patients receiving CARVYKTI® may experience fatal or life-threatening ICANS following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, ICANS occurred in 13% (36/285), including Grade ≥3 in 2% (6/285) of the patients. Median time to onset of ICANS was 8 days (range: 1 to 28 days). ICANS resolved in 30 of 36 (83%) of patients, with a median time to resolution of 3 days (range: 1 to 143 days). Median duration of ICANS was 6 days (range: 1 to 1229 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. Of patients with ICANS, 97% (35/36) had CRS. The onset of ICANS occurred during CRS in 69% of patients, before and after the onset of CRS in 14% of patients, respectively.

Immune Effector Cell-associated Neurotoxicity Syndrome occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3) and in 23% of patients in CARTITUDE-1 (3% Grade 3). The most frequent (≥2%) manifestations of ICANS included encephalopathy (12%), aphasia (4%), headache (3%), motor dysfunction (3%), ataxia (2%), and sleep disorder (2%).

Monitor patients at least daily for 7 days following CARVYKTI® infusion for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms. Monitor patients for signs or symptoms of ICANS for at least 2 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed. Advise patients to avoid driving for at least 2 weeks following infusion.

Parkinsonism: Neurologic toxicity with parkinsonism has been reported in clinical trials of CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, parkinsonism occurred in 3% (8/285), including Grade ≥3 in 2% (5/285) of the patients. Median time to onset of parkinsonism was 56 days (range: 14 to 914 days). Parkinsonism resolved in 1 of 8 (13%) of patients with a median time to resolution of 523 days. Median duration of parkinsonism was 243.5 days (range: 62 to 720 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. The onset of parkinsonism occurred after CRS for all patients and after ICANS for 6 patients.

Parkinsonism occurred in 1% of patients in CARTITUDE-4 (no Grade 3 to 4) and in 6% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Manifestations of parkinsonism included movement disorders, cognitive impairment, and personality changes. Monitor patients for signs and symptoms of parkinsonism that may be delayed in onset and managed with supportive care measures. There is limited efficacy information with medications used for the treatment of Parkinson's disease for the improvement or resolution of parkinsonism symptoms following CARVYKTI® treatment.

Guillain-Barré syndrome: A fatal outcome following GBS occurred following treatment with CARVYKTI® despite treatment with intravenous immunoglobulins. Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances, and polyradiculoneuritis.

Monitor for GBS. Evaluate patients presenting with peripheral neuropathy for GBS. Consider treatment of GBS with supportive care measures and in conjunction with immunoglobulins and plasma exchange, depending on severity of GBS.

Immune mediated myelitis: Grade 3 myelitis occurred 25 days following treatment with CARVYKTI® in CARTITUDE-4 in a patient who received CARVYKTI® as subsequent therapy. Symptoms reported included hypoesthesia of the lower extremities and the lower abdomen with impaired sphincter control. Symptoms improved with the use of corticosteroids and intravenous immune globulin. Myelitis was ongoing at the time of death from other cause.

Peripheral neuropathy occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, peripheral neuropathy occurred in 7% (21/285), including Grade ≥3 in 1% (3/285) of the patients. Median time to onset of peripheral neuropathy was 57 days (range: 1 to 914 days). Peripheral neuropathy resolved in 11 of 21 (52%) of patients with a median time to resolution of 58 days (range: 1 to 215 days). Median duration of peripheral neuropathy was 149.5 days (range: 1 to 692 days) in all patients including those with ongoing neurologic events at the time of death or data cutoff.

IMPORTANT SAFETY INFORMATION (cont)

Peripheral neuropathies occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3 to 4) and in 7% of patients in CARTITUDE-1 (2% Grade 3 to 4). Monitor patients for signs and symptoms of peripheral neuropathies. Patients who experience peripheral neuropathy may also experience cranial nerve palsies or GBS.

Cranial nerve palsies occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, cranial nerve palsies occurred in 7% (19/285), including Grade ≥3 in 1% (1/285) of the patients. Median time to onset of cranial nerve palsies was 21 days (range: 17 to 101 days). Cranial nerve palsies resolved in 17 of 19 (89%) of patients with a median time to resolution of 66 days (range: 1 to 209 days). Median duration of cranial nerve palsies was 70 days (range: 1 to 262 days) in all patients, including those with ongoing neurologic events at the time of death or data cutoff. Cranial nerve palsies occurred in 9% of patients in CARTITUDE-4 (1% Grade 3 to 4) and in 3% of patients in CARTITUDE-1 (1% Grade 3 to 4).

The most frequent cranial nerve affected was the 7th cranial nerve. Additionally, cranial nerves III, V, and VI have been reported to be affected.

Monitor patients for signs and symptoms of cranial nerve palsies. Consider management with systemic corticosteroids, depending on the severity and progression of signs and symptoms.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, HLH/MAS occurred in 1% (3/285) of patients. All events of HLH/MAS had onset within 99 days of receiving CARVYKTI®, with a median onset of 10 days (range: 8 to 99 days), and all occurred in the setting of ongoing or worsening CRS. The manifestations of HLH/MAS included hyperferritinemia, hypotension, hypoxia with diffuse alveolar damage, coagulopathy and hemorrhage, cytopenia, and multi-organ dysfunction, including renal dysfunction and respiratory failure.

Patients who develop HLH/MAS have an increased risk of severe bleeding. Monitor hematologic parameters in patients with HLH/MAS and transfuse per institutional guidelines. Fatal cases of HLH/MAS occurred following treatment with CARVYKTI®.

HLH is a life-threatening condition with a high mortality rate if not recognized and treated early. Treatment of HLH/MAS should be administered per institutional standards.

Prolonged and Recurrent Cytopenias: Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, Grade 3 or higher cytopenias not resolved by Day 30 following CARVYKTI® infusion occurred in 62% (176/285) of the patients and included thrombocytopenia 33% (94/285), neutropenia 27% (76/285), lymphopenia 24% (67/285), and anemia 2% (6/285). After Day 60 following CARVYKTI® infusion, 22%, 20%, 5%, and 6% of patients had a recurrence of Grade 3 or 4 lymphopenia, neutropenia, thrombocytopenia, and anemia, respectively, after initial recovery of their Grade 3 or 4 cytopenia. Seventy-seven percent (219/285) of patients had one, two, or three or more recurrences of Grade 3 or 4 cytopenias after initial recovery of Grade 3 or 4 cytopenia. Sixteen and 25 patients had Grade 3 or 4 neutropenia and thrombocytopenia, respectively, at the time of death.

Monitor blood counts prior to and after CARVYKTI® infusion. Manage cytopenias with growth factors and blood product transfusion support according to local institutional guidelines.

Infections: CARVYKTI® should not be administered to patients with active infection or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, infections occurred in 57% (163/285), including Grade ≥3 in 24% (69/285) of patients. Grade 3 or 4 infections with an unspecified pathogen occurred in 12%, viral infections in 6%, bacterial infections in 5%, and fungal infections in 1% of patients. Overall, 5% (13/285) of patients had Grade 5 infections, 2.5% of which were due to COVID-19. Patients treated with CARVYKTI® had an increased rate of fatal COVID-19 infections compared to the standard therapy arm.

Monitor patients for signs and symptoms of infection before and after CARVYKTI® infusion and treat patients appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to the standard institutional guidelines. Febrile neutropenia was observed in 5% of patients after CARVYKTI® infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care, as medically indicated. Counsel patients on the importance of prevention measures. Follow institutional guidelines for the vaccination and management of immunocompromised patients with COVID-19.

Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients with hypogammaglobulinemia. Perform screening for Cytomegalovirus (CMV), HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) or any other infectious agents if clinically indicated in accordance with clinical guidelines before collection of cells for manufacturing. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/ clinical practice.

Viral Reactivation (continued): Reactivation of John Cunningham (JC) virus, leading to progressive multifocal leukoencephalopathy (PML), including cases with fatal outcomes, have been reported following treatment. Perform appropriate diagnostic evaluations in patients with neurological adverse events.

Hypogammaglobulinemia can occur in patients receiving treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, hypogammaglobulinemia adverse event was reported in 36% (102/285) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 93% (265/285) of patients. Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion occurred in 94% (267/285) of patients treated. Fifty-six percent (161/285) of patients received intravenous immunoglobulin (IVIG) post CARVYKTI® for either an adverse reaction or prophylaxis.

Monitor immunoglobulin levels after treatment with CARVYKTI® and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Use of Live Vaccines: The safety of immunization with live viral vaccines during or following CARVYKTI® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during CARVYKTI® treatment, and until immune recovery following treatment with CARVYKTI®.

Hypersensitivity Reactions occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, hypersensitivity reactions occurred in 5% (13/285), all of which were ≤2 Grade. Manifestations of hypersensitivity reactions included flushing, chest discomfort, tachycardia, wheezing, tremor, burning sensation, non-cardiac chest pain, and pyrexia.

Serious hypersensitivity reactions, including anaphylaxis, may be due to the dimethyl sulfoxide (DMSO) in CARVYKTI®. Patients should be carefully monitored for 2 hours after infusion for signs and symptoms of severe reaction. Treat promptly and manage patients appropriately according to the severity of the hypersensitivity reaction.

Immune effector cell-associated enterocolitis (IEC-EC) has occurred in patients treated with CARVYKTI®. Manifestations include severe or prolonged diarrhea, abdominal pain, and weight loss requiring parenteral nutrition. IEC-EC has been associated with fatal outcome from perforation or sepsis. Manage according to institutional guidelines, including referral to gastroenterology and infectious disease specialists.

In cases of refractory IEC-EC, consider additional workup to exclude alternative etiologies, including T-cell lymphoma of the GI tract, which has been reported in the post marketing setting.

Secondary Malignancies: Patients treated with CARVYKTI® may develop secondary malignancies. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, myeloid neoplasms occurred in 5% (13/285) of patients (9 cases of myelodysplastic syndrome, 3 cases of acute myeloid leukemia, and 1 case of myelodysplastic syndrome followed by acute myeloid leukemia). The median time to onset of myeloid neoplasms was 447 days (range: 56 to 870 days) after treatment with CARVYKTI®. Ten of these 13 patients died following the development of myeloid neoplasms; 2 of the 13 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy. Cases of myelodysplastic syndrome and acute myeloid leukemia have also been reported in the post marketing setting. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®. Mature T-cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusions, and may include fatal outcomes.

Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Janssen Biotech, Inc., at 1-800-526-7736 for reporting and to obtain instructions on collection of patient samples.

ADVERSE REACTIONS

The most common nonlaboratory adverse reactions (incidence greater than 20%) are pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. The most common Grade 3 or 4 laboratory adverse reactions (incidence greater than or equal to 50%) include lymphopenia, neutropenia, white blood cell decreased, thrombocytopenia, and anemia.

Please read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

cp-258862v11

5 YEARS OF LONG-TERM FOLLOW-UP DATA

You are now viewing an analysis from the CARTITUDE-1 trial with a median duration follow-up of 61.3 months. This information is not included in the current USPI and should be interpreted with caution.

33.6 MONTHS
mDOR[6*†]

36%
of responders continued to respond at 60 months
(95% CI: 26.0-45.6)[6*†]

Safety profile[1]

- **Boxed Warning:** cytokine release syndrome (CRS), immune effector cell–associated neurotoxicity syndrome (ICANS), parkinsonism and Guillain-Barré syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), prolonged and/or recurrent cytopenias, immune effector cell-associated enterocolitis (IEC-EC), and secondary hematological malignancies
- **Warnings and precautions** include: prolonged and/or recurrent cytopenias, infections, hypogammaglobulinemia, hypersensitivity reactions, immune effector cell-associated enterocolitis (IEC-EC), and secondary malignancies
- The most common nonlaboratory **adverse reactions** (incidence >20%) included pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections of unspecified pathogen, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting

PARTNER WITH YOUR NEAREST **ACTIVATED TREATMENT CENTER** TO SEE IF YOUR PATIENTS ARE ELIGIBLE.
Scan to find your nearest certified treatment center.

Data rates may apply.

CI=confidence interval; mDOR=median duration of response; PR=partial response; USPI=United States Prescribing Information.
*Based on median follow-up of 61.3 months.[6]
†In patients who obtained PR or better (n= 94).[6]

References: 1. CARVYKTI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. *Lancet*. 2021;398(10297):314-324. **3.** Jagannath S, Martin TG, Lin Y, et al. Long-term (≥5-year) remission and survival after treatment with ciltacabtagene autoleucel in CARTITUDE-1 patients with relapsed/refractory multiple myeloma. *J Clin Oncol*. 2025;43(25):2766-2771. **4.** Usmani SZ, Berdeja JG, Madduri D, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen–directed chimeric antigen receptor t-cell therapy, in relapsed/refractory multiple myeloma: updated results from CARTITUDE-1. Oral presentation at: 2021 ASCO Annual Meeting; June 8, 2021; virtual. **5.** Madduri D, Berdeja JG, Usmani SZ, et al. CARTITUDE-1: phase 1b/2 study of ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T cell therapy, in relapsed/refractory multiple myeloma. Poster presented at: 62nd ASH Annual Meeting and Exposition; December 5-8, 2020; virtual. **6.** Data on file. Janssen Biotech, Inc. **7.** Lin Y, Martin TG, Usmani SZ, et al. CARTITUDE-1 final results: phase 1b/2 study of ciltacabtagene autoleucel in heavily pretreated patients with relapsed/refractory multiple myeloma. *J Clin Oncol*. Published online May 31, 2023. doi:10.1200/JCO.2023.41.16_suppl.8009

Please see the full Important Safety Information throughout and on pages 10-13, and read accompanying full Prescribing Information, including Boxed Warning, for CARVYKTI®.

Johnson&Johnson LEGEND BIOTECH

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion