CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

In relapsed or refractory multiple myeloma, give your patients a chance for results that are

DEEP. DURABLE. **POWERFUL.**

98%
OVERALL RESPONSE RATE
(95/97 95% CI: 92.7-99.7)[a1]

80%
STRINGENT COMPLETE RESPONSE
(78/97 95% CI: 71.1-87.8)[ab1]

14%
VERY GOOD PARTIAL RESPONSE
(14/97 95% CI: 8.1-23.0)[a1]

3%
PARTIAL RESPONSE
(3/97 95% CI: 0.6-8.8)[a1]

NOT REACHED
MEDIAN DURATION OF RESPONSE
(95% CI: 23.3-NE)[a1]

CD38=cluster of differentiation 38; CI=confidence interval; NE=not estimable.
[a]Based on a median duration of follow-up of 28 months.[1]
[b]All complete responses were stringent complete responses.[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, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.**

STUDY DESIGN[1-3]

CARTITUDE-1 was a Phase 1b/2 open-label, multicenter study evaluating the efficacy and safety of a single infusion of ciltacabtagene autoleucel in adult patients with relapsed or refractory multiple myeloma who had previously received a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

In total, 97 patients were treated with ciltacabtagene autoleucel; 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 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 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®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with CARVYKTI®.

CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

Please read the full Important Safety Information and full Prescribing Information, including Boxed Warning, for CARVYKTI®.

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PIVOTAL CARTITUDE-1 STUDY

PHASE 1b/2, OPEN-LABEL, MULTICENTER STUDY OF 97 ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA[a1,2]

Primary objectives[1,4]

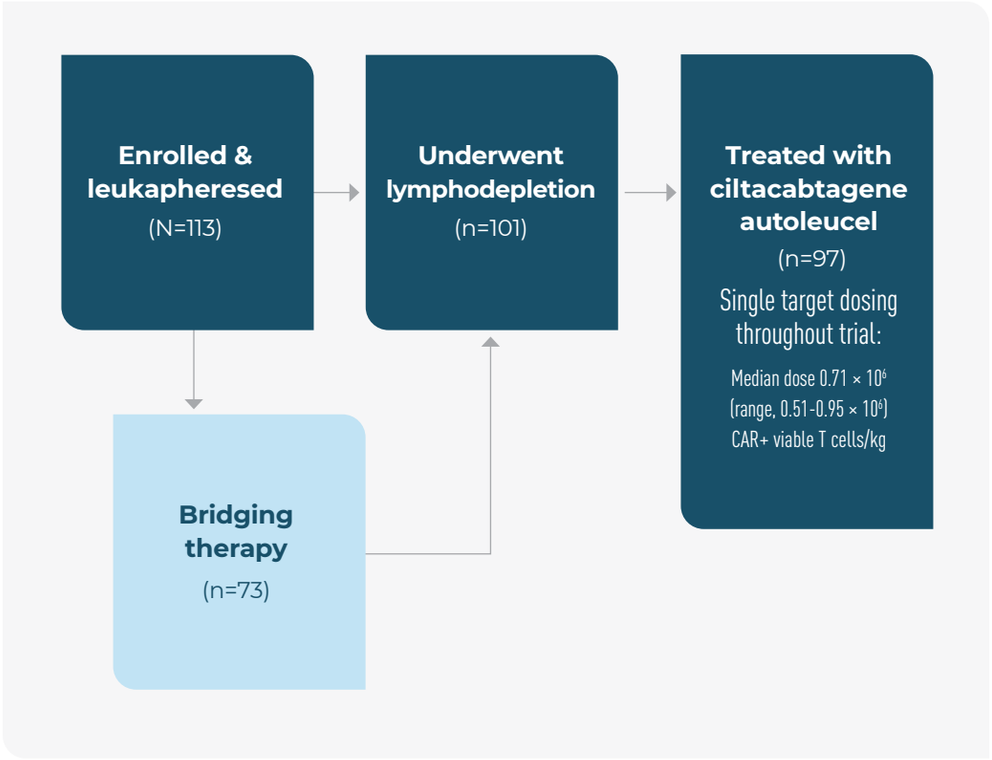
PHASE 1b:

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 ciltacabtagene autoleucel 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; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; sCR=stringent complete response; TTR=time to response; VGPR=very good partial response.

[a]See key eligibility criteria.

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. 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 and acute myeloid leukemia occurred following treatment. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

PHASE 1b/2, OPEN-LABEL, MULTICENTER STUDY OF 97 ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA[a] (cont)

Key eligibility criteria[1,2]

- Diagnosis of multiple myeloma per IMWG criteria, with measurable disease
- ≥3 previous lines of therapy (or double refractory to a proteasome inhibitor and an immunomodulatory agent)
- Previous treatment with a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- Disease progression per IMWG criteria within 12 months of last line of therapy
- ECOG performance status 0-1[b]

Exclusion criteria[1,2]

- 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^3
- Platelet count <50,000/mm^3
- Hepatic transaminases >3x the upper limit of normal
- Cardiac ejection fraction <45%
- Active serious infection
- Prior treatment with CAR-T directed at any target
- Prior therapy that is targeted to BCMA

CAR-T=chimeric antigen receptor-T cell; CNS=central nervous system; ECOG=Eastern Cooperative Oncology Group; IMWG=International Myeloma Working Group.

[b]ECOG performance status at baseline was 2 in 4% of patients.

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CARTITUDE-1 STUDY: SELECTED BASELINE CHARACTERISTICS (N=97)[1-3]

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)[a]	24% (23)
Extramedullary plasmacytomas ≥1 (n)	13% (13)[b]
Tumor BCMA expression ≥50% (n)	92% (57)[c]
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)[d]	100% (97)
Penta-exposed (n)[e]	84% (81)
Triple-class refractory (n)[d]	88% (85)
Penta-refractory (n)[e]	42% (41)
Refractory to last line of therapy (n)	99% (96)
Prior autologous stem cell transplant (n)	90% (87)
Previous allogeneic stem cell transplant (n)	8% (8)

BCMA=B-cell maturation antigen; CrCl=creatinine clearance; ECOG=Eastern Cooperative Oncology Group.

[a]Based on the presence of del(17p), t(14;16), or t(4;14).
[b]Additional 6 patients had a soft-tissue component of a bone-based plasmacytoma (total plasmacytomas, 19.6%).
[c]Denominator n=62, the number of evaluable samples; BCMA expression detected in all evaluable samples.[5]
[d]≥1 proteasome inhibitor, ≥1 immunomodulatory agent, and 1 anti-CD38 monoclonal antibody.[2]
[e]≥2 proteasome inhibitors, ≥2 immunomodulatory agents, and 1 anti-CD38 monoclonal antibody.[2]

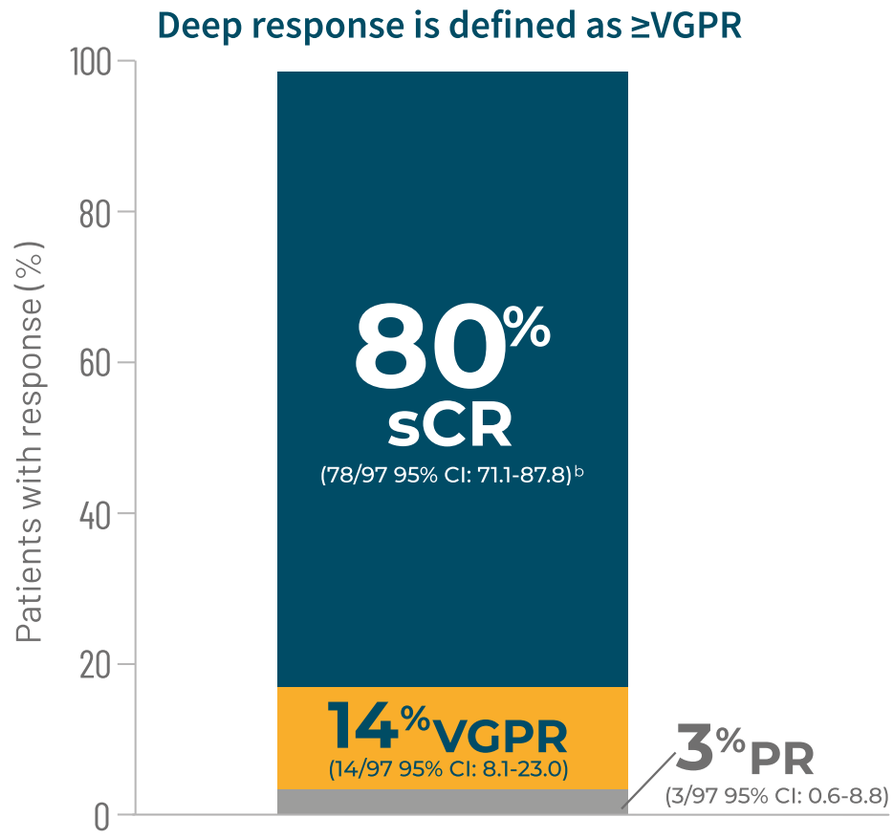
SELECTED IMPORTANT SAFETY INFORMATION

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. 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 and acute myeloid leukemia occurred following treatment. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

Median follow-up analysis: 28 months

NEARLY EVERY PATIENT ACHIEVED A CLINICAL RESPONSE AND MOST ACHIEVED DEEP RESPONSE[a1,6]

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



CI=confidence interval; ORR=overall response rate; mDOR=median duration of response; NE=not estimable; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

[a]Based on a median duration of follow-up of 28 months.[1]
[b]All complete responses were sCRs.[6]

DURABLE RESPONSE[a6]

mDOR NOT REACHED
(95% CI: 23.3-NE)[6]

Based on a median duration of follow-up of 28 months.[1]

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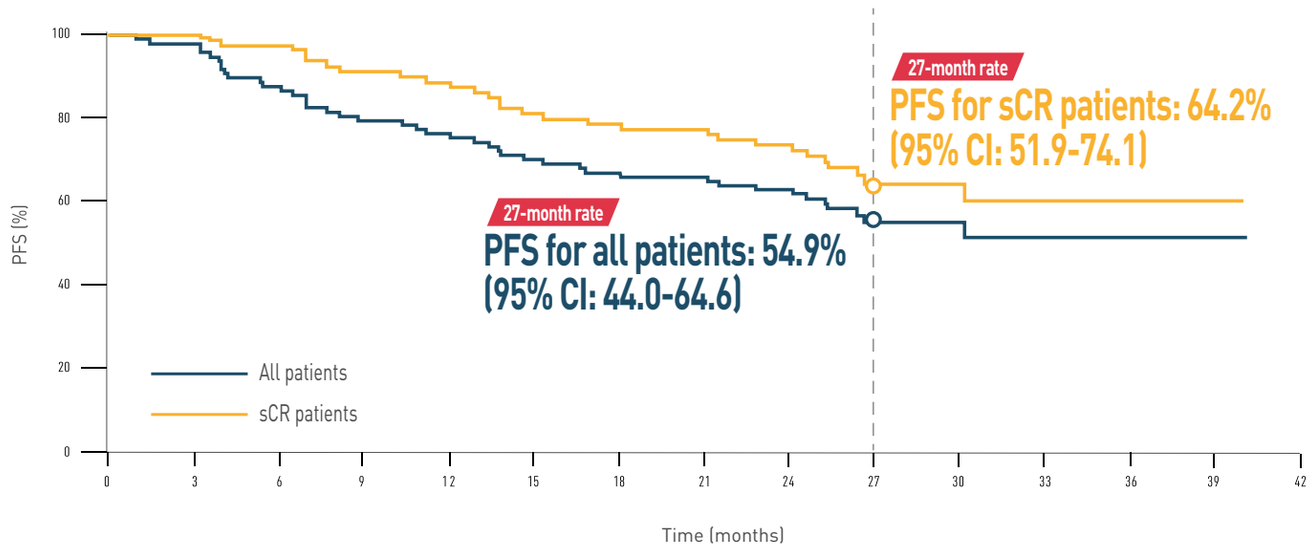
Median follow-up analysis: 28 months

PROGRESSION-FREE SURVIVAL[a6]

PFS IN CARTITUDE-1

You are now viewing an analysis from the CARTITUDE-1 trial with a median duration follow-up of 28 months. This information is not included in the current USPI and should be interpreted with caution.

- PFS was a secondary endpoint in the CARTITUDE-1 trial and could not be statistically tested in the setting of a single-arm trial
- The data are presented here for descriptive purposes only



No. at risk:

All patients	97	95	85	77	74	67	64	63	57	27	17	3	1	1	0
sCR patients	80	80	78	73	71	64	62	61	55	27	17	3	1	1	0

As of January 11, 2022, which was the data cutoff, 66 of the 97 patients who received cilta-cel infusion remain in the study. Thirty patients have died and 1 withdrew from the study

mPFS NOT REACHED
for all patients
(95% CI: 24.5-NE)

CI=confidence interval; mPFS=median progression-free survival; NE=not estimable; PFS=progression-free survival; sCR=stringent complete response; USPI=US Prescribing Information.

[a]Based on a median duration of follow-up of 27.7 months.[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. 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 and acute myeloid leukemia occurred following treatment. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

Median follow-up analysis: 28 months

OVERALL SURVIVAL[a6]

OS IN CARTITUDE-1

You are now viewing an analysis from the CARTITUDE-1 trial with a median duration follow-up of 28 months. This information is not included in the current USPI and should be interpreted with caution.

- OS was a secondary endpoint in the CARTITUDE-1 trial and could not be statistically tested in the setting of a single-arm trial
- The statistical significance of OS is not known
- The data are presented here for descriptive purposes only

Median OS was not reached

The 27-month OS rate in the overall population was 70.4%
(95% CI: 60.1-78.6)

As of January 11, 2022, which was the data cutoff, 66 of the 97 patients who received cilta-cel infusion remain in the study. Thirty patients have died and 1 withdrew from the study

CI=confidence interval; OS=overall survival; USPI=US Prescribing Information.

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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 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®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with CARVYKTI®.

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WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS) including fatal or life-threatening reactions, occurred following treatment with CARVYKTI® in 95% (92/97) of patients receiving ciltacabtagene autoleucel. Grade 3 or higher CRS (2019 ASTCT grade) occurred in 5% (5/97) of patients, with Grade 5 CRS reported in 1 patient. The median time to onset of CRS was 7 days (range: 1-12 days). The most common manifestations of CRS included pyrexia (100%), hypotension (43%), increased aspartate aminotransferase (AST) (22%), chills (15%), increased alanine aminotransferase (ALT) (14%) and sinus tachycardia (11%). Grade 3 or higher events associated with CRS included increased AST and ALT, hyperbilirubinemia, hypotension, pyrexia, hypoxia, respiratory failure, acute kidney injury, disseminated intravascular coagulation and hemorrhage, HLH/MAS, angina pectoris, supraventricular and ventricular tachycardia, malaise, myalgias, increased C-reactive protein, ferritin, blood alkaline phosphatase and gamma-glutamyl transferase.

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. One patient with CRS and suspected HLH/MAS developed a fatal retroperitoneal hemorrhage in the setting of thrombocytopenia, coagulopathy and anticoagulation in another ongoing study of CARVYKTI®.

Sixty-nine of 97 (71%) patients received tocilizumab and/or a corticosteroid for CRS after infusion of ciltacabtagene autoleucel. Forty-four (45%) patients received only tocilizumab, of whom 33 (34%) received a single dose and 11 (11%) received more than one dose; 24 patients (25%) received tocilizumab and a corticosteroid, and one patient (1%) received only corticosteroids. Ensure that a minimum of two doses of tocilizumab are available prior to infusion of CARVYKTI®.

Monitor patients at least daily for 10 days following CARVYKTI® infusion at a REMS-certified healthcare facility for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 4 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, Guillain-Barré Syndrome, 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.

Overall, one or more subtypes of neurologic toxicity described below occurred following ciltacabtagene autoleucel in 26% (25/97) of patients, of which 11% (11/97) of patients experienced Grade 3 or higher events. These subtypes of neurologic toxicities were also observed in two ongoing studies.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS): Patients 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. ICANS occurred in 23% (22/97) of patients receiving ciltacabtagene autoleucel including Grade 3 or 4 events in 3% (3/97) and Grade 5 (fatal) events in 2% (2/97). The median time to onset of ICANS was 8 days (range 1-28 days). All 22 patients with ICANS had CRS. The most frequent (≥5%) manifestation of ICANS included encephalopathy (23%), aphasia (8%) and headache (6%).

Monitor patients at least daily for 10 days following CARVYKTI® infusion at the REMS-certified healthcare facility for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms. Monitor patients for signs or symptoms of ICANS for at least 4 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Parkinsonism: Of the 25 patients in the CARTITUDE-1 study experiencing any neurotoxicity, six male patients had neurologic toxicity with several signs and symptoms of parkinsonism, distinct from immune effector cell-associated neurotoxicity syndrome (ICANS). Neurologic toxicity with parkinsonism has been reported in other ongoing trials of ciltacabtagene autoleucel. Patients had parkinsonian and non-parkinsonian symptoms that included tremor, bradykinesia, involuntary movements, stereotypy, loss of spontaneous movements, masked facies, apathy, flat affect, fatigue, rigidity, psychomotor retardation, micrographia, dysgraphia, apraxia, lethargy, confusion, somnolence, loss of consciousness, delayed reflexes, hyperreflexia, memory loss, difficulty swallowing, bowel incontinence, falls, stooped posture, shuffling gait, muscle weakness and wasting, motor dysfunction, motor and sensory loss, akinetic mutism, and frontal lobe release signs. The median onset of parkinsonism in the 6 patients in CARTITUDE-1 was 64 days (range 14-914 days) from infusion of ciltacabtagene autoleucel.

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 Guillain-Barré Syndrome (GBS) has occurred in another ongoing study of ciltacabtagene autoleucel despite treatment with intravenous immunoglobulin (IVIG). 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 immunoglobulin and plasma exchange, depending on severity of GBS.

Immune Mediated Myelitis: Grade 3 myelitis has occurred 25 days following treatment in another ongoing study. 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: Seven patients in CARTITUDE-1 developed peripheral neuropathy. These neuropathies presented as sensory, motor or sensorimotor neuropathies. Median time of onset of symptoms was 66 days (range 4-914 days), median duration of peripheral neuropathies was 138 days (range 2-692 days) including those with ongoing neuropathy. Patients who experienced peripheral neuropathy also experienced cranial nerve palsies or GBS in other ongoing trials of ciltacabtagene autoleucel. Monitor patients for signs and symptoms of peripheral neuropathies.

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

IMPORTANT SAFETY INFORMATION (cont)

Cranial Nerve Palsies: Three patients (3.1%) experienced cranial nerve palsies in CARTITUDE-1. All three patients had 7th cranial nerve palsy; one patient had 5th cranial nerve palsy as well. Median time to onset was 26 days (range 21-101 days) following infusion of ciltacabtagene autoleucel. Occurrence of 3rd and 6th cranial nerve palsy, bilateral 7th cranial nerve palsy, worsening of cranial nerve palsy after improvement, and occurrence of peripheral neuropathy in patients with cranial nerve palsy have also been reported in ongoing trials of ciltacabtagene autoleucel. 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): Fatal HLH occurred in one patient (1%), 99 days after ciltacabtagene autoleucel. The HLH event was preceded by prolonged CRS lasting 97 days. The manifestations of HLH/MAS include hypotension, hypoxia with diffuse alveolar damage, coagulopathy, cytopenia, and multi-organ dysfunction, including renal dysfunction.

One patient with Grade 4 HLH/MAS developed fatal intracerebral and gastrointestinal hemorrhage in the setting of coagulopathy and thrombocytopenia 12 days after treatment in another ongoing study. Patients who develop HLH/MAS have an increased risk of severe bleeding. Monitor hematological parameters in patients with HLH/MAS and transfuse per institutional guidelines.

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.

CARVYKTI® REMS: Because of the risk of CRS and neurologic toxicities, CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS.

Further information is available at https://www.carvyktirems.com/ or 1-844-672-0067.

Prolonged and Recurrent Cytopenias: Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion. One patient underwent autologous stem cell therapy for hematopoietic reconstitution due to prolonged thrombocytopenia.

In CARTITUDE-1, 30% (29/97) of patients experienced prolonged Grade 3 or 4 neutropenia and 41% (40/97) of patients experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Day 30 following ciltacabtagene autoleucel infusion.

Recurrent Grade 3 or 4 neutropenia, thrombocytopenia, lymphopenia and anemia were seen in 63% (61/97), 19% (18/97), 60% (58/97), and 37% (36/97) after recovery from initial Grade 3 or 4 cytopenia following infusion. After Day 60 following ciltacabtagene autoleucel infusion, 31%, 12% and 6% of patients had a recurrence of Grade 3 or higher lymphopenia, neutropenia and thrombocytopenia, respectively, after initial recovery of their Grade 3 or 4 cytopenia. Eighty-seven percent (84/97) 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. Eight and 12 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.

Infections (all grades) occurred in 57 (59%) patients. Grade 3 or 4 infections occurred in 21% (20/97) of patients; Grade 3 or 4 infections with an unspecified pathogen occurred in 15%, viral infections in 7%, bacterial infections in 1%, and fungal infections in 1% of patients. Overall, 5 patients had Grade 5 infections: lung abscess (n=1), sepsis (n=3) and pneumonia (n=1).

Grade 5 infections reported in other studies include bronchopulmonary aspergillosis, pneumocystis jirovecii pneumonia, and CMV colitis (with HSV-1 hepatitis). Another patient developed mycotic aneurysm due to cerebral aspergillosis and died of subarachnoid hemorrhage.

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 10% of patients after ciltacabtagene autoleucel 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.

In a randomized controlled study of relapsed or refractory multiple myeloma (CARTITUDE-4), patients treated with ciltacabtagene autoleucel had an increased rate of fatal COVID-19 infections compared to the standard therapy arm. 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.

Hypogammaglobulinemia was reported as an adverse event in 12% (12/97) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 92% (89/97) of patients. 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 have occurred in 5% (5/97) of patients following ciltacabtagene autoleucel infusion. 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 appropriately according to the severity of the hypersensitivity reaction.

Secondary Malignancies: Patients treated with CARVYKTI® may develop secondary malignancies. Myeloid neoplasms (five cases of myelodysplastic syndrome, three cases of acute myeloid leukemia and two cases of myelodysplastic syndrome followed by acute myeloid leukemia) occurred in 10% (10/97) of patients in CARTITUDE-1 study following treatment with CARVYKTI®. The median time to onset of myeloid neoplasms was 485 days (range: 162 to 1040 days) after treatment with CARVYKTI®. Nine of these 10 patients died following the development of myeloid neoplasms; four of the 10 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. Monitor life-long 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.

Effects on Ability to Drive and Use Machines: Due to the potential for neurologic events, including altered mental status, seizures, neurocognitive decline, or neuropathy, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following CARVYKTI® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery during this initial period, and in the event of new onset of any neurologic toxicities.

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence greater than 20%) are 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. The most common laboratory adverse reactions (incidence greater than or equal to 50%) include thrombocytopenia, neutropenia, anemia, aminotransferase elevation, and hypoalbuminemia.

cp-258862v7

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

CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE[a]

CYTOKINE RELEASE SYNDROME (CRS)[1,2]

CRS, including fatal or life-threatening reactions, occurred after ciltacabtagene autoleucel infusion

ANY GRADE	GRADE 3-4	GRADE 5
95% (n=92/97)	**4%** (n=4/97)	**1%** (n=1/97)

MEDIAN TIME TO ONSET OF CRS
7 DAYS
(range, 1-12 days)

MEDIAN DURATION OF CRS
4 DAYS
(range, 1-40 days) with one patient extending out to 97 days

- Some patients required tocilizumab, corticosteroids, and/or anakinra for management of CRS
- Sixty-nine of 97 patients (71%) received tocilizumab and/or a corticosteroid for CRS after infusion of ciltacabtagene autoleucel. Forty-four patients (45%) received only tocilizumab; 24 patients (25%) received tocilizumab and a corticosteroid, and one patient (1%) received only corticosteroids
- Ensure that a minimum of 2 doses of tocilizumab are available for each patient prior to CARVYKTI® infusion and during recovery period, if needed for treatment of CRS
- In patients with early onset of fever (if onset less than 72 hours after infusion), tocilizumab should be considered
- At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids, depending on CRS grade (see Table 1 in Prescribing Information)
- Evaluation for hemophagocytic lymphohistiocytosis should be considered in patients with severe or unresponsive CRS

HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH)[1]

HLH is a potentially life-threatening complication

- In the CARTITUDE-1 study, one patient had a duration of CRS of 97 days, which was complicated by secondary HLH with a subsequent fatal outcome
- Other monoclonal antibodies targeting cytokines (for example, anti-IL1 and/or anti-TNFα) or therapy directed at reduction and elimination of CAR-T cells may be considered for patients who develop high-grade CRS and HLH that remain severe or life-threatening following prior administration of tocilizumab and corticosteroids
- One patient with grade 4 HLH/MAS developed fatal intracerebral and gastrointestinal hemorrhage in the setting of coagulopathy and thrombocytopenia 12 days after treatment in another ongoing study of CARVYKTI®. Patients who develop HLH/MAS have an increased risk of severe bleeding. Monitor hematological parameters in patients with HLH/MAS and transfuse per institutional guidelines

CAR-T=chimeric antigen receptor-T cell; IL1=interleukin-1; TNFα=tumor necrosis factor alpha.

[a]Safety data were collected from CARTITUDE-1 and other ongoing trials.[1]

NEUROLOGIC TOXICITIES[1]

Neurologic toxicities, which may be severe, life-threatening, or fatal, occurred following treatment with ciltacabtagene autoleucel

ANY GRADE	GRADE 3 OR HIGHER
26% (n=25/97)	**11%** (n=11/97)

IMMUNE EFFECTOR CELL–ASSOCIATED NEUROTOXICITY SYNDROME (ICANS)[1]

ANY GRADE	GRADE 3-4	GRADE 5
23% (n=22/97)	**3%** (n=3/97)	**2%** (n=2/97)

MEDIAN TIME TO FIRST ONSET OF ICANS
8 DAYS
(range, 1-28 days)

MEDIAN DURATION OF ICANS
7.5 DAYS
(range, 2-1229 days)

- ICANS resolved in 17 of 22 patients (77%), and the median time to resolution was 6 days (range, 2-143 days)
- The onset of ICANS occurred during CRS in 16 patients, before the onset of CRS in 3 patients, and after the CRS event in 3 patients
- Median duration of ICANS in all patients—including those with fatal ICANS, ICANS ongoing at time of death from other causes, or ongoing at last known alive date—was 7.5 days (range, 2-1229 days)
- All 22 patients with ICANS had CRS
- Counsel patients to seek immediate medical attention should signs and symptoms of neurotoxicity occur after recovery from CRS and/or ICANS
- Provide intensive care and supportive therapy for severe or life-threatening neurologic toxicities

CRS=cytokine release syndrome.

Please read the full Important Safety Information and full Prescribing Information, including Boxed Warning, for CARVYKTI®.

SAFETY PROFILE[a] (cont)

NEUROLOGIC TOXICITIES (cont)

Parkinsonism

- Of the 25 patients in the CARTITUDE-1 study experiencing any neurotoxicity, six male patients had neurologic toxicity with several signs and symptoms of parkinsonism, distinct from ICANS
- Neurologic toxicity with parkinsonism has been reported in other ongoing trials of ciltacabtagene autoleucel. Patients had parkinsonian and nonparkinsonian symptoms that included tremor, bradykinesia, involuntary movements, stereotypy, loss of spontaneous movements, masked facies, apathy, flat affect, fatigue, rigidity, psychomotor retardation, micrographia, dysgraphia, apraxia, lethargy, confusion, somnolence, loss of consciousness, delayed reflexes, hyperreflexia, memory loss, difficulty swallowing, bowel incontinence, falls, stooped posture, shuffling gait, muscle weakness and wasting, motor dysfunction, motor and sensory loss, akinetic mutism, and frontal lobe release signs
- The median onset of parkinsonism in the 6 patients in CARTITUDE-1 was 64 days (range, 14-914 days) from infusion of ciltacabtagene autoleucel
- 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 and for the improvement or resolution of parkinsonism symptoms following CARVYKTI® treatment

Guillain-Barré syndrome (GBS)

- A fatal outcome following GBS has occurred in another ongoing study of ciltacabtagene autoleucel despite treatment with intravenous immunoglobulin (IVIG). 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 immunoglobulin and plasma exchange, depending on severity of GBS

Immune-mediated myelitis

- Grade 3 myelitis has occurred 25 days following treatment with CARVYKTI® in another ongoing study. Symptoms reported included hypoesthesia of the lower extremities and the lower abdomen with impaired sphincter control. Symptoms improved with the use of corticosteroids and IVIG. Myelitis was ongoing at the time of death from other cause

Peripheral neuropathy

- Seven patients in CARTITUDE-1 developed peripheral neuropathy. These neuropathies presented as sensory, motor or sensorimotor neuropathies. Median time of onset of symptoms was 66 days (range, 4-914 days), and the median duration of peripheral neuropathies was 138 days (range, 2-692 days) including those with ongoing neuropathy. Patients who experienced peripheral neuropathy also experienced cranial nerve palsies or GBS in other ongoing trials of ciltacabtagene autoleucel
- Monitor patients for signs and symptoms of peripheral neuropathies

Cranial nerve palsies

- Three patients (3.1%) experienced cranial nerve palsies in CARTITUDE-1. All 3 patients had 7th cranial nerve palsy; one patient had 5th cranial nerve palsy as well. Median time to onset was 26 days (range, 21-101 days) following infusion of ciltacabtagene autoleucel. Occurrence of 3rd and 6th cranial nerve palsy, bilateral 7th cranial nerve palsy, worsening of cranial nerve palsy after improvement, and occurrence of peripheral neuropathy in patients with cranial nerve palsy have also been reported in ongoing trials of ciltacabtagene autoleucel
- 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

[a]Safety data were collected from CARTITUDE-1 and other ongoing trials.

PROLONGED AND/OR RECURRENT CYTOPENIAS

- Prolonged Grade 3 or 4 neutropenia was experienced by 30% (n=29) of patients
- Forty-one percent (n=40) of patients experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Day 30 following ciltacabtagene autoleucel infusion
- Recurrent Grade 3 or 4 neutropenia, thrombocytopenia, lymphopenia, and anemia were seen in 63% (61/97), 19% (18/97), 60% (58/97), and 37% (36/97) of patients, respectively, after recovery from initial Grade 3 or 4 cytopenia following ciltacabtagene autoleucel infusion
- After Day 60 following ciltacabtagene autoleucel infusion, 31%, 12%, and 6% of patients had a recurrence of Grade 3 or higher lymphopenia, neutropenia, and thrombocytopenia, respectively, after initial recovery from their Grade 3 or 4 cytopenia

HEMATOLOGIC ADVERSE REACTIONS

Grade 3-4 hematologic laboratory abnormalities occurring in ≥10% of patients in CARTITUDE-1 (N=97)

LABORATORY ABNORMALITY	GRADE 3-4 (%)
LYMPHOPENIA	99
NEUTROPENIA	98
WHITE BLOOD CELLS DECREASED	98
ANEMIA	72
THROMBOCYTOPENIA	63
ASPARTATE AMINOTRANSFERASE INCREASED	21

SECONDARY MALIGNANCIES

- Myeloid neoplasms (five cases of myelodysplastic syndrome, three cases of acute myeloid leukemia and two cases of myelodysplastic syndrome followed by acute myeloid leukemia) occurred in 10% (10/97) of patients in CARTITUDE-1 study following treatment with CARVYKTI®.
- The median time to onset of myeloid neoplasms was 485 days (range: 162 to 1040 days)after treatment with CARVYKTI®.
- Nine of these 10 patients died following the development of myeloid neoplasms.
- Four of the 10 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy.
- Monitor life-long 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.

Please read the full Important Safety Information and full Prescribing Information, including Boxed Warning, for CARVYKTI®.

SAFETY PROFILE[a] (cont)

ADVERSE REACTIONS (≥10%) (N=97)

ADVERSE REACTIONS	ALL GRADES (%)	GRADE ≥3 (%)
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

[a]Safety data were collected from CARTITUDE-1 and other ongoing trials.

ADVERSE REACTIONS (≥10%) (N=97) (cont)

ADVERSE REACTIONS	ALL GRADES (%)	GRADE ≥3 (%)
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 (INCL CYSTS AND POLYPS)		
Hematologic malignancy	10	10
VASCULAR DISORDERS		
Hypotension	51	10
Hypertension	19	6
Hemorrhage	16	4

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CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

MONITORING AND MANAGEMENT[1]

Delay the infusion of CARVYKTI® if your patient encounters:

- Clinically significant active infection or inflammatory disorders
- Grade ≥3 nonhematologic toxicities of cyclophosphamide and fludarabine conditioning, except for Grade 3 nausea, vomiting, diarrhea, or constipation. CARVYKTI® infusion should be delayed until resolution of these events to Grade ≤1

Monitoring patients

- Patients will be monitored daily for **10 days** at a certified healthcare facility following CARVYKTI® infusion for signs and symptoms of CRS and neurologic toxicity
- Monitor patients periodically for at least 4 weeks after infusion for signs and symptoms of CRS and neurologic toxicity and treat promptly
- Instruct patients to remain within proximity of a certified healthcare facility for at least 4 weeks following infusion
- Counsel patients to seek immediate medical attention should signs or symptoms of CRS or neurologic toxicity occur at any time

CARVYKTI® IS ONLY AVAILABLE THROUGH A RESTRICTED PROGRAM UNDER A RISK EVALUATION AND MITIGATION STRATEGY (REMS) CALLED CARVYKTI® REMS

VISIT **CARVYKTIREMS.com**

CRS=cytokine release syndrome.

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. 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 and acute myeloid leukemia occurred following treatment. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

SUPPORT FOR CARVYKTI® PATIENTS AND CAREGIVERS

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

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

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

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

TO GET YOUR PATIENTS STARTED, CONTACT A MyCARVYKTI® PATIENT SUPPORT SPECIALIST AT

1-800-559-7875

MONDAY TO FRIDAY, 8:00 AM TO 8:00 PM EASTERN TIME

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.** A study of JNJ-68284528, a chimeric antigen receptor T cell (CAR-T) therapy directed against B-cell maturation antigen (BCMA) in participants with relapsed or refractory multiple myeloma (CARTITUDE-1). ClinicalTrials.gov identifier: NCT03548207. Updated October 6, 2022. Accessed March 29, 2023. https://www.clinicaltrials.gov/ct2/show/NCT03548207 **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: Virtual 62nd American Society of Clinical Oncology (ASCO) Annual Meeting & Exposition; June 4-8, 2021; presentation #8005. **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.** Martin T, Usmani SZ, Berdeja JG, et al. Ciltacabtagene autoleucel, an anti–B-cell maturation antigen chimeric antigen receptor T-cell therapy, for relapsed/refractory multiple myeloma: CARTITUDE-1 2-year follow-up. *J Clin Oncol*. 2022;JCO2200842. doi:10.1200/JCO.22.00842 **7.** Data on file Janssen Biotech, Inc.

Please read the full Important Safety Information and full Prescribing Information, including Boxed Warning, for CARVYKTI®.

In relapsed or refractory multiple myeloma, give your patients a chance for results that are

DEEP. DURABLE. **POWERFUL.**

INDICATIONS

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, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.**

Deep and durable responses after a one-time infusion[a][1]

- 98% ORR (95/97 95% CI: 92.7-99.7)
- 80% sCR (78/97 95% CI: 71.1-87.8)[b]
- 14% VGPR (14/97 95% CI: 8.1-23.0)
- 3% PR (3/97 95% CI: 0.6-8.8)
- mDOR: not reached (95% CI: 23.3-NE)

An analysis of CARTITUDE-1 with a median duration of 28 months:

- mPFS and mOS: not reached

PFS and OS were secondary endpoints in the CARTITUDE-1 trial and could not be statistically tested in the setting of a single-arm trial.
PFS and OS are not in in the USPI and should be interpreted with caution.

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, secondary hematological malignancies, and Risk Evaluation and Mitigation Strategy (REMS)
- **Warnings and precautions** include: prolonged and/or recurrent cytopenias, infections, hypogammaglobulinemia, hypersensitivity reactions, secondary malignancies, effects on ability to drive and use machines
- 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

MyCARVYKTI® PATIENT SUPPORT PROGRAM

1-800-559-7875

MONDAY TO FRIDAY, 8:00 AM TO 8:00 PM EASTERN TIME

CD38=cluster of differentiation 38; CI=confidence interval; mDOR=median duration of response; mOS=median overall survival; mPFS=median progression-free survival; NE=not estimable; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PR=partial response; sCR=stringent complete response; USPI=US Prescribing Information; VGPR=very good partial response.

[a]Based on a median duration of follow-up of 28 months.[1]
[b]All complete responses were sCRs.[1]

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LEGEND BIOTECH

CARVYKTI®
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