CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

EXPLORE LONG-TERM FOLLOW-UP ANALYSIS ON PAGES 6-8

Give your adult patients with RRMM who have received a PI and an immunomodulatory agent, and are lenalidomide-refractory, a chance for

POWERFUL RESULTS AS EARLY AS 2L[1]

PRESCRIBED CAR-T CELL THERAPY FOR RRMM[2†] #1

CARVYKTI® demonstrated a

59% **Reduction in the risk of disease progression or death vs standard therapy (DPd or PVd)**
(HR=0.41; 95% CI: 0.30-0.56; *P*<0.0001)[1]*

STUDY DESIGN

CARTITUDE-4 is a phase 3 randomized, open label, multicenter trial evaluating the efficacy and safety of CARVYKTI® for the treatment of patients with relapsed and lenalidomide-refractory multiple myeloma, who previously received at least 1 prior line of therapy including a PI and an immunomodulatory agent. A total of 419 patients were randomized to receive either CARVYKTI® (n=208) or standard therapy, which included physician's choice of daratumumab, pomalidomide, and dexamethasone (DPd) or pomalidomide, bortezomib, and dexamethasone (PVd) (n=211). The primary efficacy measure was PFS analyzed based on the Intent-to-Treat Analysis Set.[1]

2L=second-line; CAR-T=chimeric antigen receptor-T cell; CI=confidence interval; HR=hazard ratio; PFS=progression-free survival; PI=proteasome inhibitor; RRMM=relapsed or refractory multiple myeloma.
*15.9-month median follow-up (Intent-to-Treat Analysis Set).
†From January 2021 to November 2024.

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.

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®.

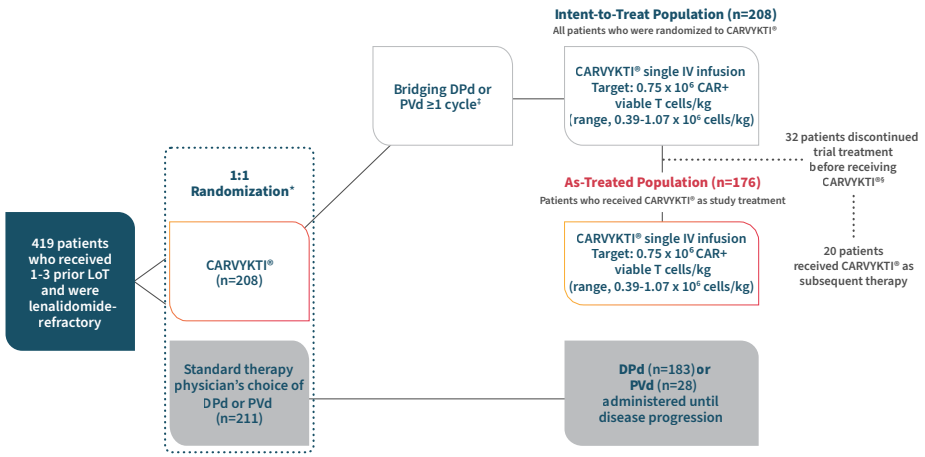
Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous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

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

TABLE OF CONTENTS

CARTITUDE-4 STUDY DESIGN[1,3]

CARTITUDE-4 is a 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).



Primary Endpoint:
PFS (Intent-to-Treat)†

Select Secondary Endpoints‖:
CR or better, ORR (sCR + CR + VGPR + PR), OS

CAR+=chimeric antigen receptor-positive; CR=complete response; IMWG=International Myeloma Working Group; IRC=Independent Review Committee; ISS=International Staging System; IV=intravenous infusion; LoT=line(s) of therapy; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

*Randomization was stratified by physician's choice of treatment (DPd or PVd), ISS (I vs II vs III), and number of prior lines of therapy (1 vs 2 or 3).

†Per the IMWG consensus, assessed by IRC.

‡80.8% of patients received 1 to 2 cycles of standard therapy. Maximum received was 6 cycles in 1 patient.

§The remaining 32 patients discontinued trial participation before receiving CARVYKTI®, predominantly because of disease progression during bridging therapy or lymphodepletion. Of these patients, 20 received CARVYKTI® as a subsequent therapy.[1]

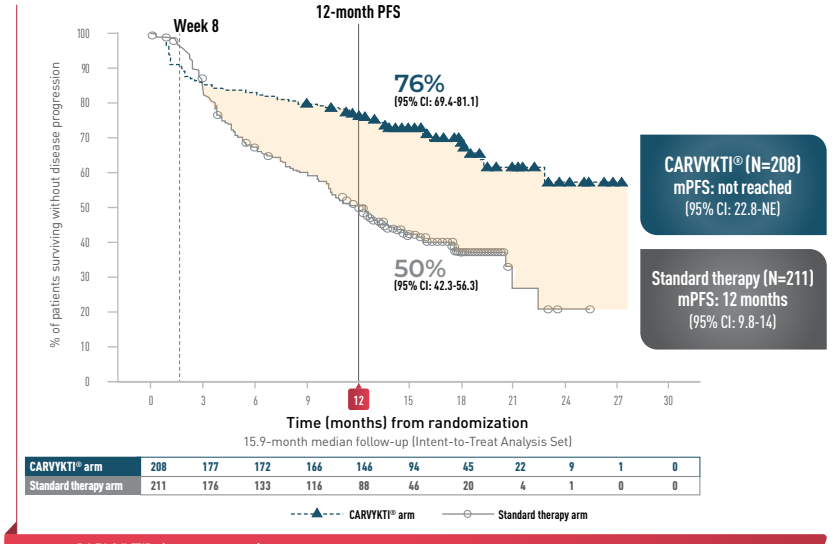
‖Secondary outcomes were sequentially tested at each prespecified significance level, including (in order) rates of CR or better, ORR.[3]

POWERFUL RESULTS

CARTITUDE-4 MEDIAN FOLLOW-UP OF 15.9 MONTHS

CARVYKTI® SIGNIFICANTLY PROLONGED PROGRESSION-FREE SURVIVAL (PRIMARY ENDPOINT) VS STANDARD THERAPY (DPd OR PVd)[1]*

PROGRESSION-FREE SURVIVAL



CARVYKTI® arm	208	177	172	166	146	94	45	22	9	1	0
Standard therapy arm	211	176	133	116	88	46	20	4	1	0	0

CARVYKTI® demonstrated a **↓59%** **Reduction in the risk of disease progression or death vs standard therapy (DPd or PVd)** (HR=0.41; 95% CI: 0.30-0.56; *P*<0.0001)[1]*

Percentages rounded to nearest whole number.

CAR-T=chimeric antigen receptor-T cell; CI=confidence interval; DPd=daratumumab, pomalidomide, and dexamethasone; HR=hazard ratio; mPFS=median progression-free survival; NE=not estimable; PFS=progression-free survival; PVd=pomalidomide, bortezomib, and dexamethasone.

*Median follow-up was 15.9 months in the Intent-to-Treat Analysis Set.

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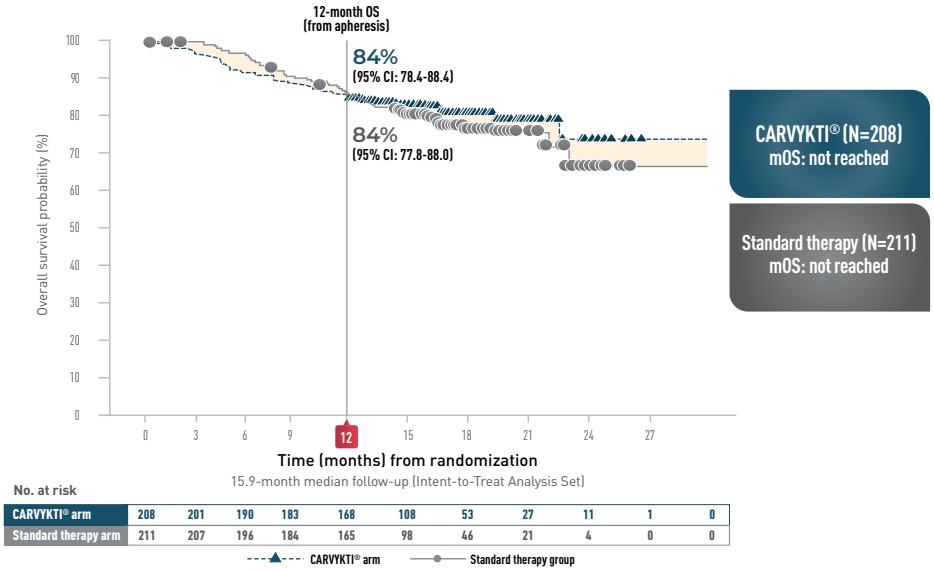
OVERALL SURVIVAL

CARTITUDE-4 MEDIAN FOLLOW-UP OF 15.9 MONTHS*

MEDIAN OVERALL SURVIVAL (OS) WAS NOT REACHED[1]

OVERALL SURVIVAL[1,2*]



- **34% of the planned OS events have occurred**
- **Within the first 10 months of randomization, a higher proportion of patients in the CARVYKTI® arm died compared to the standard therapy arm. See Infusion and Monitoring Considerations on page 13.**

CI=confidence interval; mOS=median overall survival; OS=overall survival.
*Median follow-up was 15.9 months in the Intent-to-Treat Analysis Set.

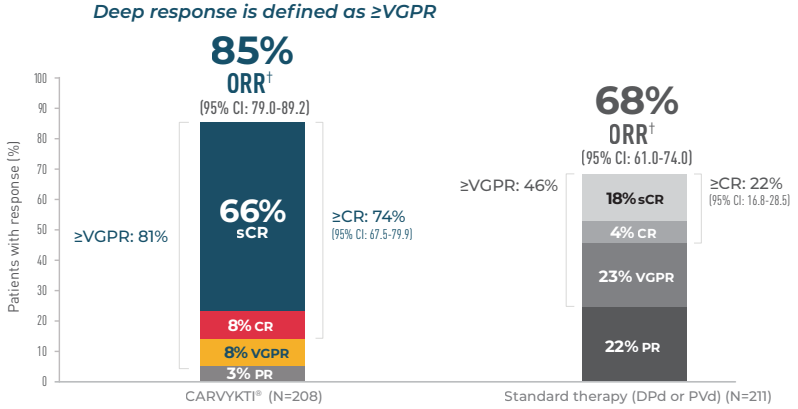
PRIMARY ANALYSIS

DEEP RESPONSES[2]

CARTITUDE-4 MEDIAN FOLLOW-UP OF 15.9 MONTHS*

85% OVERALL RESPONSE RATE WAS ACHIEVED WITH CARVYKTI®, AND 81% OF PATIENTS ACHIEVED A DEEP RESPONSE[1,3*]

OVERALL RESPONSE RATE



DURABLE RESPONSES

MEDIAN DURATION OF RESPONSE FOR CARVYKTI® WAS NOT REACHED[1*]

- **mDOR was not reached in patients who achieved PR or better or in patients who achieved CR or better vs 16.6 months with standard therapy (95% CI: 12.9-NE)[1*‡]**

Percentages rounded to nearest whole number and may not add up due to rounding.
CI=confidence interval; CR=complete response; DPd=daratumumab, pomalidomide, and dexamethasone; mDOR=median duration of response; NE=not estimable; ORR=overall response rate; PR=partial response; PVd=pomalidomide, bortezomib, and dexamethasone; sCR=stringent complete response; VGPR=very good partial response.
*Median follow-up was 15.9 months in the Intent-to-Treat Analysis Set.
†Includes patients who achieved PR or better.
‡Estimated mDOR.

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

CARTITUDE-4 MEDIAN FOLLOW-UP OF 15.9 MONTHS*

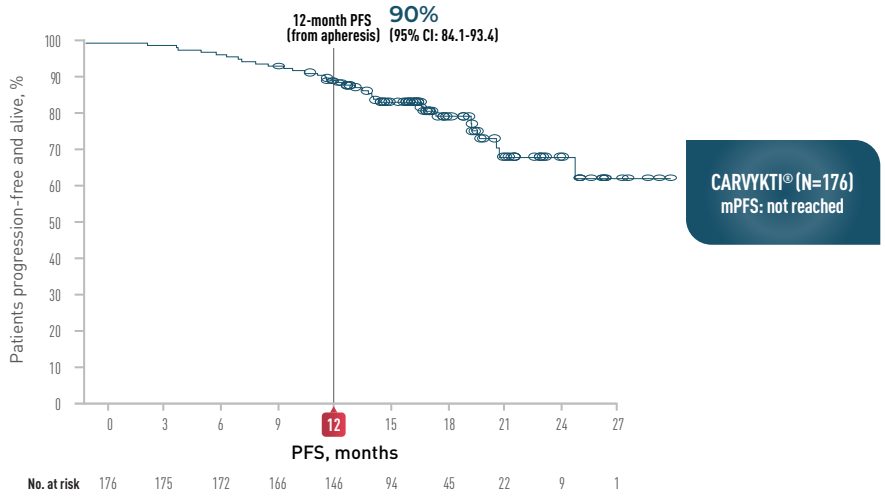
AS-TREATED PATIENT POPULATION

OVERALL RESPONSE RATE

CARTITUDE-4 MEDIAN FOLLOW-UP OF 15.9 MONTHS*

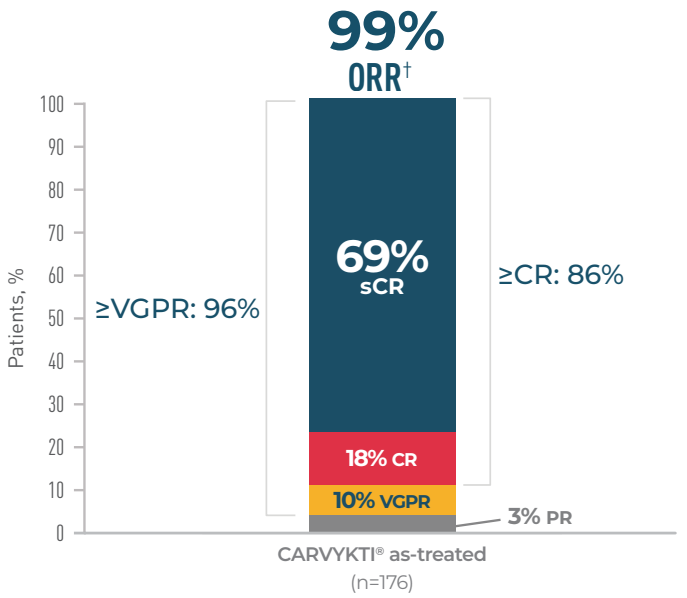
The following data are based on a post hoc analysis of patients that received cilta-cel as study treatment. Patients who progressed or died prior to cilta-cel infusion were excluded from this analysis. Therefore, these data should be interpreted with caution and considered as supportive evidence regarding cilta-cel efficacy. This information is not contained in the USPI.

PROGRESSION-FREE SURVIVAL[4,5]



Percentage rounded to nearest whole number.
CI=confidence interval; mPFS=median progression-free survival; PFS=progression-free survival; USPI=US Prescribing Information.
*Median follow-up was 15.9 months in the As-Treated Analysis Set.

OVERALL RESPONSE RATE[4]*



Percentages rounded to nearest whole number and may not add up due to rounding.
CR=complete response; ORR=overall response rate; PR=partial response; sCR=stringent complete response; USPI=US Prescribing Information; VGPR=very good partial response.
*Median follow-up was 15.9 months in the As-Treated Analysis Set.
†Includes patients who achieved PR or better.

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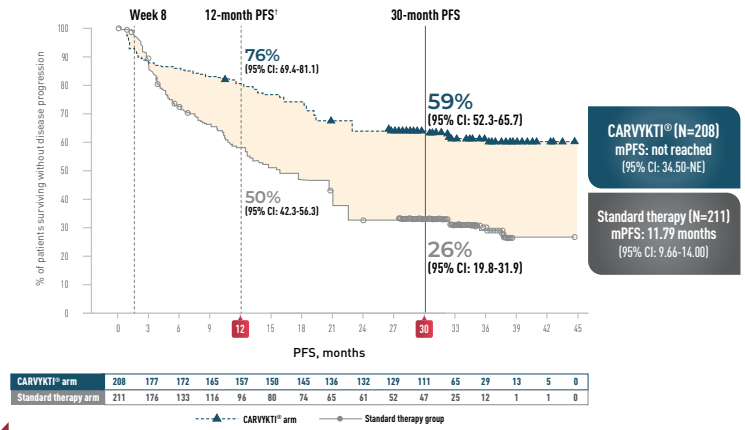
PROGRESSION-FREE SURVIVAL

CARTITUDE-4 MEDIAN FOLLOW-UP OF 33.6 MONTHS*

PROGRESSION-FREE SURVIVAL[1-3,6]



CARVYKTI® demonstrated a **↓71%** Reduction in the risk of disease progression or death vs standard therapy (DPd or PVd) (HR=0.29; 95% CI: 0.22-0.39)[5*‡]

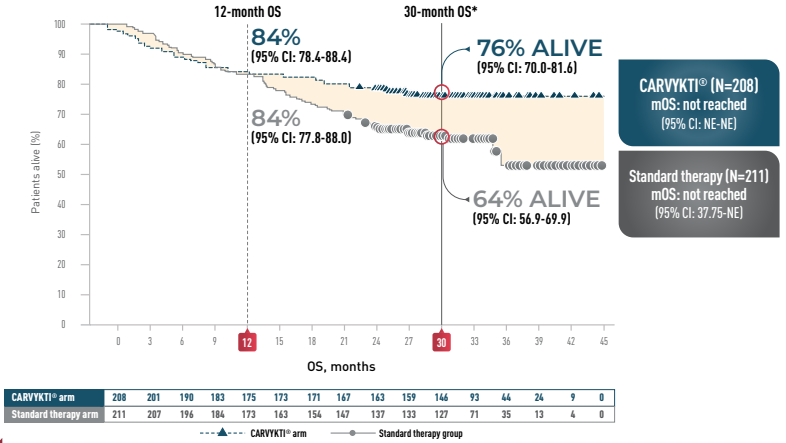
Percentages rounded to nearest whole number. This data is calculated from a weighted analysis.
CI=confidence interval; DPd=daratumumab, pomalidomide, and dexamethasone; FDA=US Food and Drug Administration; HR=hazard ratio; mPFS=median progression-free survival; NE=not estimable; PFS=progression-free survival; PVd=pomalidomide, bortezomib, and dexamethasone; USPI=US Prescribing Information.
*Median follow-up was 33.6 months in the Intent-to-Treat Analysis Set.
†12-month PFS values are derived from the USPI and are based on independent review committee (IRC) assessment of progression, FDA-requested analysis approach for PFS, and the 01 November 2022 data cutoff.
‡HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable, including only PFS events that occurred >8 weeks post randomization.

CARVYKTI® DEMONSTRATED A STATISTICALLY SIGNIFICANT OS BENEFIT IN 2L+[2]

CARTITUDE-4 MEDIAN FOLLOW-UP OF 33.6 MONTHS*

You are now viewing a subsequent follow-up analysis of the CARTITUDE-4 trial. This information is not included in the current USPI and should be interpreted with caution. The data are presented here for descriptive purposes only.

OVERALL SURVIVAL[1-3,6*†]



CARVYKTI® demonstrated a **↓45%** Reduction in the risk of death vs standard therapy (DPd or PVd) (HR=0.55; 95% CI: 0.39-0.79; *P*=0.0009)[5*†]

Percentages rounded to nearest whole number.
2L=second-line; CI=confidence interval; DPd=daratumumab, pomalidomide, and dexamethasone; HR=hazard ratio; mOS=median overall survival; NE=not estimable; OS=overall survival; PVd=pomalidomide, bortezomib, and dexamethasone; USPI=US Prescribing Information.
*Median follow-up was 33.6 months in the Intent-to-Treat Analysis Set.
†Hazard ratio and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable.

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

CARTITUDE-4 MEDIAN FOLLOW-UP OF 33.6 MONTHS*†

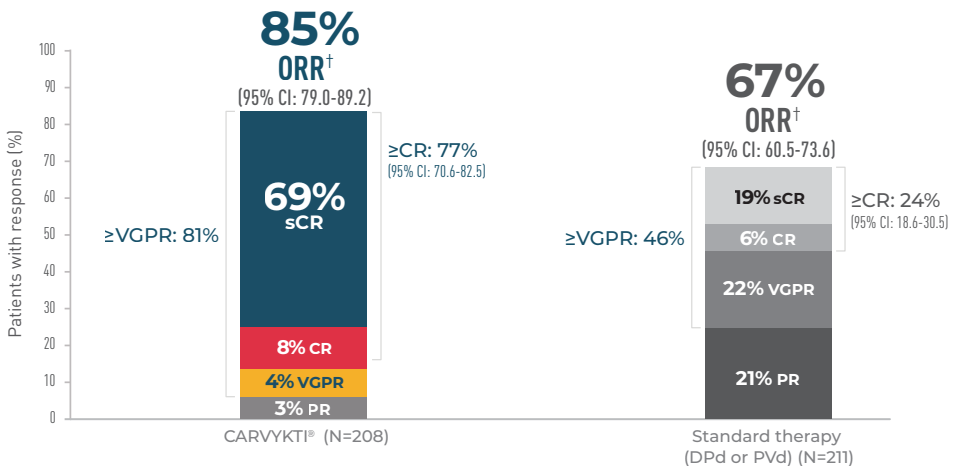
33.6-MONTH FOLLOW-UP ANALYSIS

DURATION OF RESPONSE

CARTITUDE-4 MEDIAN FOLLOW-UP OF 33.6 MONTHS*

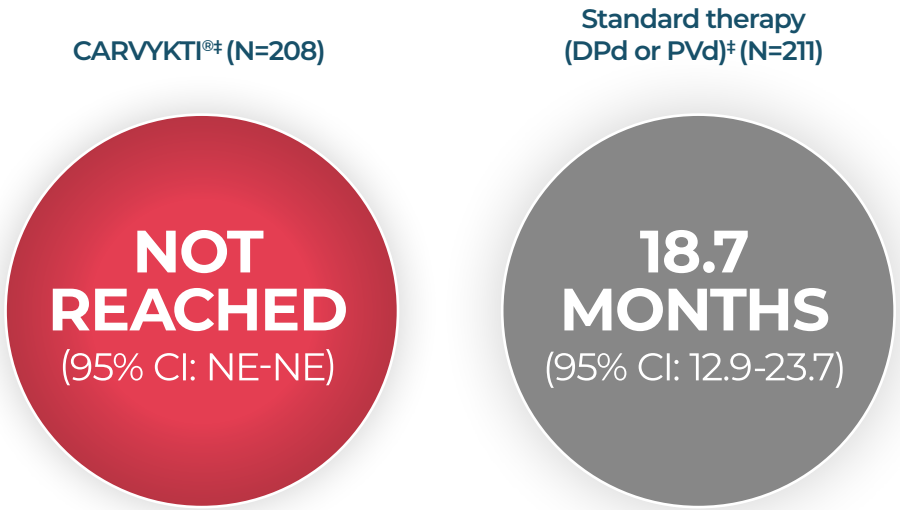
You are now viewing a subsequent follow-up analysis of the CARTITUDE-4 trial. This information is not included in the current USPI and should be interpreted with caution. The data are presented here for descriptive purposes only.

OVERALL RESPONSE RATE[2,6]*



Percentages rounded to nearest whole number and may not add up due to rounding.
CI=confidence interval; CR=complete response; DPd=daratumumab, pomalidomide, and dexamethasone; IMWG=International Myeloma Working Group; ORR=overall response rate; PR=partial response; PVd=pomalidomide, bortezomib, and dexamethasone; sCR=stringent complete response; USPI=US Prescribing Information; VGPR=very good partial response.
*Median follow-up was 33.6 months in the Intent-to-Treat Analysis Set.
†Assessed using a validated computerized algorithm; ORR is defined as the proportion of subjects who achieve a PR or better per IMWG criteria.

MEDIAN DURATION OF RESPONSE[6†]



CI=confidence interval; DOR=duration of response; DPd=daratumumab, pomalidomide, and dexamethasone; mDOR=median duration of response; NE=not estimable; PVd=pomalidomide, bortezomib, dexamethasone; USPI=US Prescribing Information.
*Median follow-up was 33.6 months in the Intent-to-Treat Analysis Set.
†Analyzed among responders.
‡Estimated mDOR.

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

CARTITUDE-4 MEDIAN FOLLOW-UP OF 33.6 MONTHS*

You are now viewing a subsequent follow-up analysis of the CARTITUDE-4 trial. This information is not included in the current USPI.

The safety data described in this section reflect the CARTITUDE-4 follow-up safety analysis at 33.6 months. The safety population of CARVYKTI® represents all patients who were randomized to CARVYKTI® (N=208)[6]*

INFECTIONS	CARVYKTI® (N=208)	STANDARD THERAPY (N=208)
Treatment-emergent infections, (%)		
All Grade	63.5	76.4
Grade 3/4	28.4	29.8
Deaths due to TE- and non-TE infections, n	16	19
In first year, n	13	8
In second year, n	2	8

CAUSE OF DEATH	CARVYKTI® (N=208)	STANDARD THERAPY (N=208)
Deaths, n	**50**	**82**
Due to progressive disease	21	51
Due to TEAE	12	8

SECONDARY PRIMARY MALIGNANCIES	CARVYKTI® (N=208)	STANDARD THERAPY (N=208)
SPMs, n (%)	**27 (13.0)**	**24 (11.5)**
Hematologic,† n (%)	7 (3.4)	1 (0.5)
MDS, n	4	0
Progressed to AML, n	2	–
AML, n	1	0
Peripheral T-cell lymphoma, n	2	0
EBV-associated lymphoma, n	0	1
Cutaneous/non-invasive†	15 (7.2)	15 (7.2)
Non-cutaneous/invasive†	6 (2.9)	8 (3.8)

- **Both arms had Grade 3/4 TEAE around 97%; most frequently cytopenia**
- **There have been no additional incidences of cranial nerve palsy or MNT since the previous data cutoff, as reported by San-Miguel J, et al in the *NEJM* 15.9-month follow-up, whether patients received CARVYKTI® as study treatment (n=176) or received CARVYKTI® as subsequent therapy[3]**
  - **Among the patients who received CARVYKTI® as a study treatment (n=176) in CARTITUDE-4, there are a total of 16 cases of CNP, of which 14 cases recovered, and 1 case of ongoing MNT[3]**

AML=acute myeloid leukemia; CNP=cranial nerve palsy; EBV=Epstein-Barr virus; LT=long term; MDS=myelodysplastic syndrome; MNT=movement and neurocognitive treatment-emergent adverse event; SPM=secondary primary malignancy; TE=treatment-emergent; TEAE=treatment-emergent adverse event; USPI=US Prescribing Information.
*Median was 33.6 months (follow-up analysis) and 15.9 months (primary analysis) in the Intent-to-Treat Analysis Set.
†Multiple SPMs could occur in the same patient.

CONSIDER CARVYKTI® FOR PATIENTS AS EARLY AS 2L[1,3,6]*

Regardless of SCT eligibility and high-risk factors, CARVYKTI® may be right for your patients with RRMM.

2L | 3L

	Terry	Margaret	Chris	Lucy
				
Clinical Considerations	55 years old **High-risk cytogenetics** ECOG PS: 0	70 years old **Standard-risk cytogenetics** ECOG PS: 0	67 years old **Standard-risk cytogenetics** ECOG PS: 0 Transplant-eligible/ deferred	81 years old **Standard-risk cytogenetics** ECOG PS: 1
Treatment History	**1L:** DVRd→SCT→R maintenance Relapse after 3 years	**1L:** VRd→SCT→R maintenance Progression after 5 years	**1L:** VRd→SCT→R maintenance Progression after 40 months **2L:** DKd Progression after 20 months	**1L:** DRd Progression after 42 months **2L:** PVd Progression after 12 months

Transplant-Eligible | Transplant-Ineligible

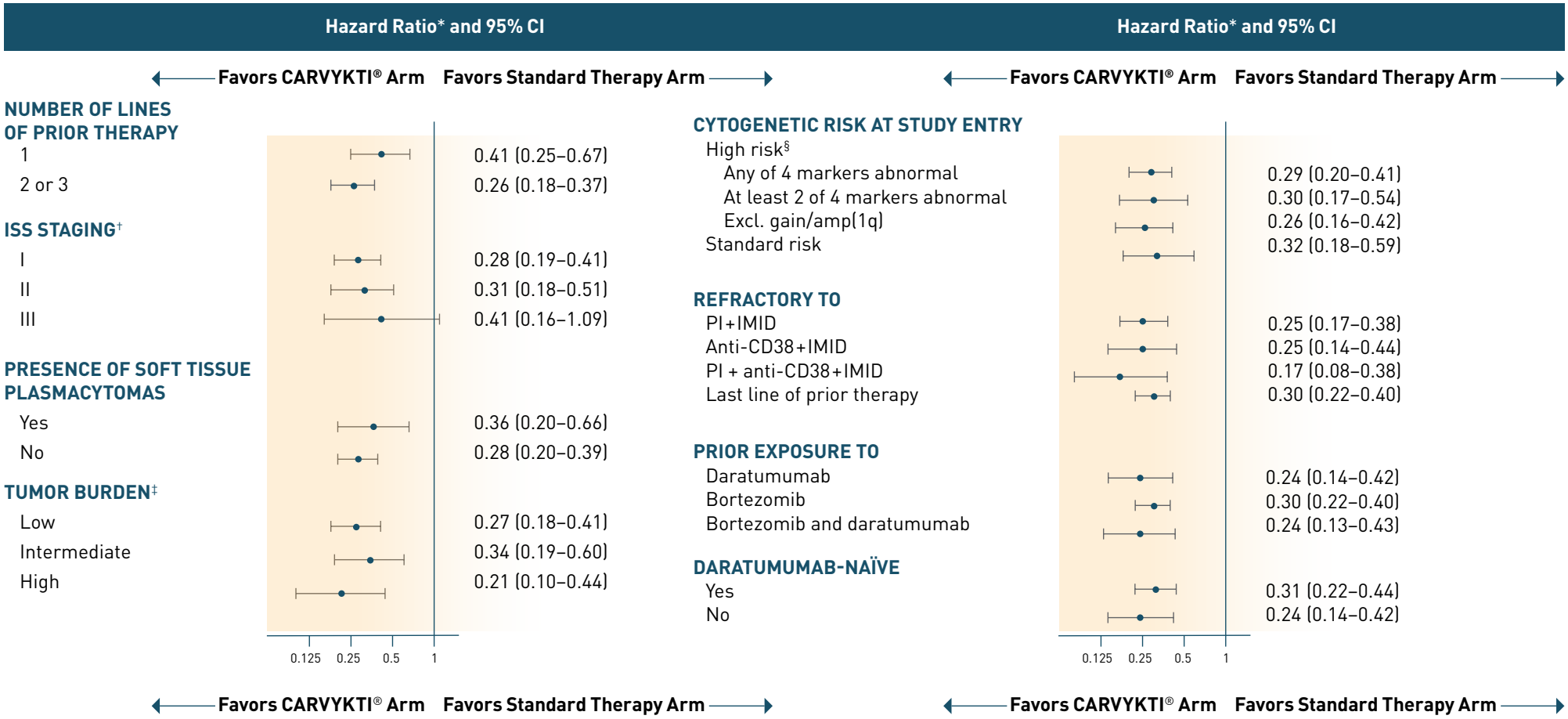
1L=first-line; 2L=second-line; 3L=third-line; DKd=daratumumab, carfilzomib, dexamethasone; DRd=daratumumab, lenalidomide, dexamethasone; DVRd=daratumumab, bortezomib, lenalidomide, dexamethasone; ECOG PS=Eastern Cooperative Oncology Group performance status; PVd=pomalidomide, bortezomib, dexamethasone; R=lenalidomide; RRMM=relapsed or refractory multiple melanoma; SCT=stem cell transplant; VRd=bortezomib, lenalidomide, dexamethasone.

*Patient cases do not represent all characteristics for CARVYKTI® eligibility.

EFFICACY OF CARVYKTI® ACROSS ALL SUBGROUPS[6]

You are now viewing a subsequent follow-up analysis of the CARTITUDE-4 trial. This information is not included in the current USPI and should be interpreted with caution. The data are presented here for descriptive purposes only.

PROGRESSION-FREE SURVIVAL SUBGROUP FOLLOW-UP ANALYSIS (33.6 MONTHS)



CD38=cluster of differentiation 38; CI=confidence interval; del=deletion; FISH=fluorescence in situ hybridization; HR=hazard ratio; IMID=immunomodulatory agent; ISS=International Staging System; PFS=progression-free survival; PI=proteasome inhibitor; t=translocation.

*HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable, including only PFS events that occurred >8 weeks post randomization.

†Based on serum β2-microglobulin and albumin.

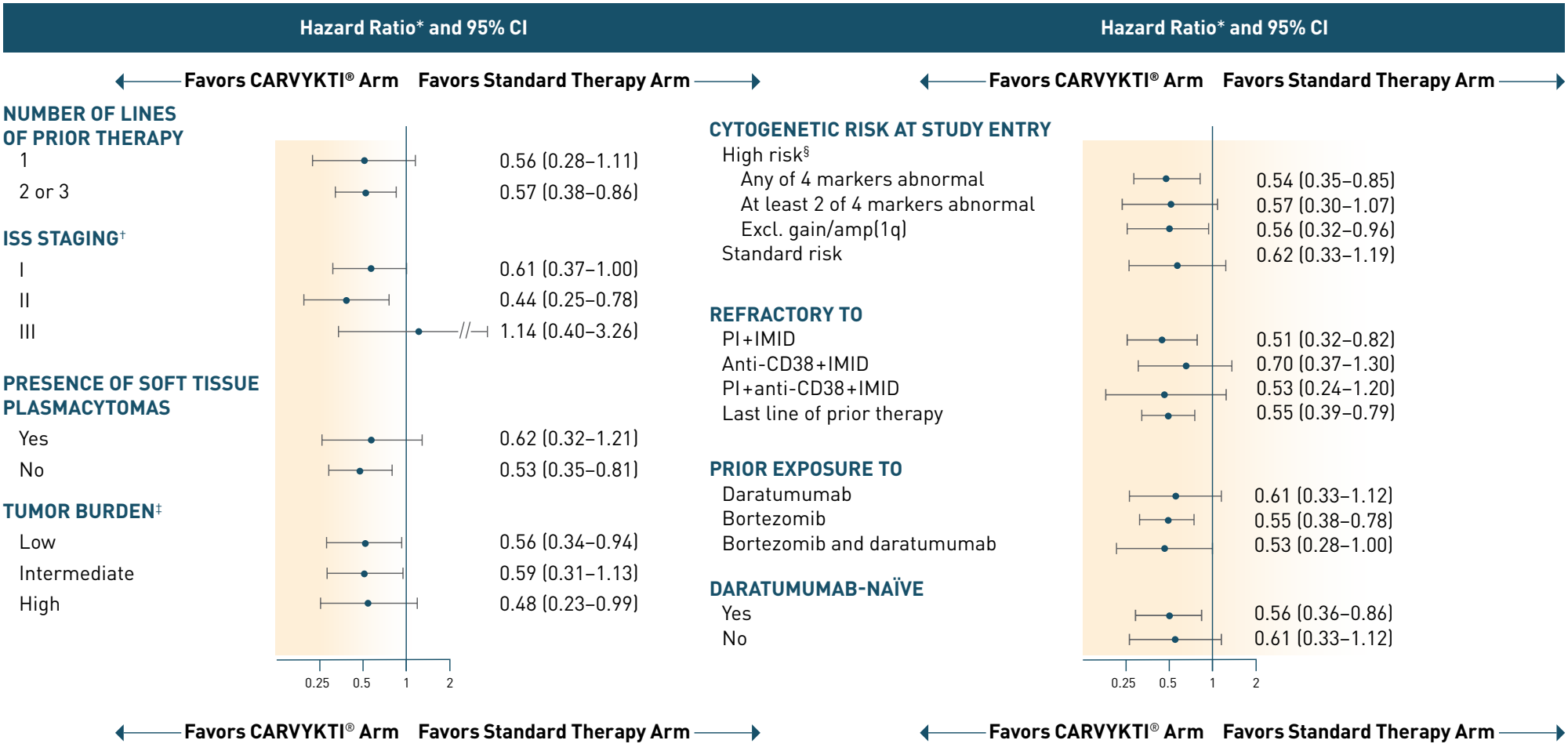
‡Low tumor burden defined as meeting all following parameters (as applicable): bone marrow % plasma cell <50%, serum M-protein <3 g/dL, serum free light chain <3000 mg/L; high tumor burden defined as meeting any of the following parameters: bone marrow % plasma cell ≥80%, serum M-protein ≥5 g/dL, serum free light chain ≥5000 mg/L; intermediate tumor burden did not fit either criteria of high or low tumor burden.

§Positive for del(17p), t(14;16), t(4;14), and/or gain/amp(1q) by FISH testing. Protocol-defined high-risk cytogenetics refers to "Any of 4 markers abnormal."

EFFICACY OF CARVYKTI® ACROSS ALL SUBGROUPS[6]

You are now viewing a subsequent follow-up analysis of the CARTITUDE-4 trial. This information is not included in the current USPI and should be interpreted with caution. The data are presented here for descriptive purposes only.

OVERALL SURVIVAL SUBGROUP FOLLOW-UP ANALYSIS (33.6 MONTHS)



CD38=cluster of differentiation 38; CI=confidence interval; del=deletion; FISH=fluorescence in situ hybridization; HR=hazard ratio; IMID=immunomodulatory drug; ISS=International Staging System; PI=proteasome inhibitor; t=translocation.

*HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable. HR <1 indicates an advantage for the cilta-cel arm.

†Based on serum β2-microglobulin and albumin.

‡Low tumor burden defined as meeting all following parameters (as applicable): bone marrow % plasma cell <50%, serum M-protein <3 g/dL, serum free light chain <3000 mg/L; high tumor burden defined as meeting any of the following parameters: bone marrow % plasma cell ≥80%, serum M-protein ≥5 g/dL, serum free light chain ≥5000 mg/L; intermediate tumor burden did not fit either criteria of high or low tumor burden.

§Positive for del(17p), t(14;16), t(4;14), and/or gain/amp(1q) by FISH testing. Protocol-defined high-risk cytogenetics refers to "Any of 4 markers abnormal."

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®.

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®.

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

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.

Ensure that a minimum of two 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 one dose of corticosteroids for treatment of CRS.

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.

WARNINGS AND PRECAUTIONS (cont'd)

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 cut off. 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 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: 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 cut off. 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

WARNINGS AND PRECAUTIONS (cont'd)

(range: 1 to 692 days) in all patients including those with ongoing neurologic events at the time of death or data cut off.

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 cut off. 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.

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.

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,

WARNINGS AND PRECAUTIONS (cont'd)

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.

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 500mg/dl after infusion in 93% (265/285) of patients. Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500mg/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 ≤Grade 2. 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.

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 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 receiving CARVYKTI® 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 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-258862v9

CARVYKTI® HAS A WELL-STUDIED SAFETY PROFILE ACROSS MULTIPLE LINES OF THERAPY IN RRMM[1,3,7]

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 IMID agent. See page 3 for full study design.

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

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

CARTITUDE-1 is a Phase 1b/2, open-label, multicenter trial of 97 adult patients with relapsed or refractory multiple myeloma who previously received at least 3 prior lines of therapy including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody.

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.

CD38=cluster of differentiation 38; CRS=cytokine release syndrome; HLH=hemophagocytic lymphohistiocytosis; ICANS=immune effector cell-associated neurotoxicity syndrome; IMID=immunomodulatory drug; MAS=macrophage activation 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. A numerically higher percent of early mortality was observed as compared to the control arm in CARTITUDE-4. 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. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.
cp-300288v4

LONG-TERM MONITORING FOR SERIOUS ADVERSE REACTIONS

LONG-TERM MONITORING

LONG-TERM MONITORING

The following side effects may continue to present and/or occur 4 weeks or more after CARVYKTI® infusion:

- Cytokine release syndrome
- Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome
- Parkinsonism
- Guillain-Barré Syndrome
- Immune mediated myelitis
- Peripheral neuropathy
- Cranial nerve palsies
- Hemophagocytic lymphohistiocytosis/ Macrophage Activation Syndrome
- Prolonged and/or recurrent cytopenias
- Serious infections including febrile neutropenia
- Hypogammaglobulinemia
- Secondary malignancies

Due to the potential for neurologic events, including altered mental status, seizures, neurocognitive decline or neuropathy, patients receiving CARVYKTI® 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.

Educate your patient and their care partner on identifying symptoms of potential side effects, when they happen, and how to report them to healthcare providers on the multidisciplinary team

Continued communication and collaboration is essential for patient transition to long-term monitoring and follow-up, including the importance of care partner support

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

VISIT CARVYKTIREMS.com

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. 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. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program. cp-300288v4

CYTOKINE RELEASE SYNDROME (CRS)

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

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

ANY GRADE	GRADE ≥3 (2019 ASTCT Grade)
84% (n=238/285)	4% (n=11/285)

MEDIAN TIME TO ONSET	MEDIAN DURATION
7 DAYS (range, 1-23 days)	4 DAYS (range, 1-97 days)

- Cytokine release syndrome resolved in 82% with a median duration of 4 days (range, 1-97 days)
- The most common manifestations of CRS in all patients combined (≥10%) included fever (84%), hypotension (29%), and aspirate 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
- 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
- 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 one dose of corticosteroids for treatment of CRS

In CARTITUDE-4 (N=188)

ANY GRADE	GRADE 3-4
78%	3%

In CARTITUDE-1 (N=97)

ANY GRADE	GRADE 3-4
95%	4%

ASTCT=American Society of Transplantation and Cellular Therapy; HLH=hemophagocytic lymphohistiocytosis; MAS=macrophage activation syndrome; USPI=US Prescribing Information.
*See CARVYKTI® USPI Table 1 CRS grading and management guidance.

NEUROLOGIC TOXICITIES

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

Neurologic toxicities, which may be severe, life-threatening, or fatal, occurred after CARVYKTI® infusion

ANY GRADE	GRADE ≥3
24% (n=69/285)	7% (n=19/285)

- The median time to onset was 10 days (range, 1-101 days) 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, 1-544 days)
- 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.

ANY GRADE	GRADE ≥3
13% (n=36/285)	2% (n=6/285)

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

MEDIAN DURATION
6 DAYS
(range, 1-1229 days)

- ICANS resolved in 30 of 36 (83%) of patients with a median time to resolution of 3 days (range, 1-143 days)
- 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
- 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 10 days following CARVYKTI® infusion at the CARVYKTI® Certified Treatment Center 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

In CARTITUDE-4 (N=188)

ANY GRADE	GRADE 3
7%	0.5%

In CARTITUDE-1 (N=97)

ANY GRADE	GRADE 3
23%	3%

CRS=cytokine release syndrome; USPI=US Prescribing Information.
*See CARVYKTI® USPI Table 2 Guidance for management of ICANS.

NEUROLOGIC TOXICITIES (cont'd)

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

PARKINSONISM

ANY GRADE	GRADE ≥3
3% (n=8/285)	2% (n=5/285)

MEDIAN TIME TO ONSET
56 DAYS
(range, 14-914 days)

MEDIAN DURATION
243.5 DAYS
(range, 62-720 days)

- Parkinsonism resolved in 1 of 8 (13%) of patients with a median time to resolution of 523 days
- The 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

In CARTITUDE-4 (N=188)

ANY GRADE	GRADE 3-4
1%	0%

In CARTITUDE-1 (N=97)

ANY GRADE	GRADE 3-4
6%	4%

GUILLAIN-BARRÉ SYNDROME (GBS)

- 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

NEUROLOGIC TOXICITIES (cont'd)

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

PERIPHERAL NEUROPATHY

ANY GRADE	GRADE ≥3
7% (n=21/285)	1% (n=3/285)

MEDIAN TIME TO ONSET
57 DAYS
(range, 1-914 days)

MEDIAN DURATION
149.5 DAYS
(range, 1-692 days)

- Peripheral neuropathy resolved in 11 of 21 (52%) of patients with a median time to resolution of 58 days (range, 1-215 days)
- Monitor patients for signs and symptoms of peripheral neuropathies
- Patients who experience peripheral neuropathy may also experience cranial nerve palsies or GBS

In CARTITUDE-4 (N=188)

ANY GRADE	GRADE 3-4
7%	0.5%

In CARTITUDE-1 (N=97)

ANY GRADE	GRADE 3-4
7%	2%

CRANIAL NERVE PALSIES

ANY GRADE	GRADE ≥3
7% (n=19/285)	1% (n=1/285)

MEDIAN TIME TO ONSET
21 DAYS
(range, 17-101 days)

MEDIAN DURATION
70 DAYS
(range, 1-262 days)

- Cranial nerve palsies resolved in 17 of 19 (89%) of patients, with a median time to resolution of 66 days (range, 1-209 days)
- 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

In CARTITUDE-4 (N=188)

ANY GRADE	GRADE 3-4
9%	1%

In CARTITUDE-1 (N=97)

ANY GRADE	GRADE 3-4
3%	1%

GBS=Guillain-Barré Syndrome.

HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS/ MACROPHAGE ACTIVATION SYNDROME (HLH/MAS)

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

HLH/MAS is a potentially life-threatening complication

ANY GRADE
1% (n=3/285)

MEDIAN TIME TO ONSET
10 DAYS
(range, 8-99 days)

- All events of HLH/MAS 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

CRS=cytokine release syndrome.

PROLONGED AND/OR RECURRENT CYTOPENIAS

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion

PROLONGED AND/OR RECURRENT CYTOPENIAS

- 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

HEMATOLOGIC ADVERSE EVENTS IN CARTITUDE-4

Grade 3 or 4 laboratory abnormalities in ≥10% of patients treated with CARVYKTI® (N=188) and standard therapy (N=208)

LABORATORY ABNORMALITY	CARVYKTI® (N=188)	STANDARD THERAPY (N=208)
LYMPHOCYTE COUNT DECREASED	99	62
NEUTROPHIL COUNT DECREASED	95	88
WHITE BLOOD CELLS DECREASED	94	69
PLATELET COUNT DECREASED	47	20
HEMOGLOBIN DECREASED	34	17

HEMATOLOGIC ADVERSE EVENTS IN CARTITUDE-1

Grade 3 or 4 laboratory abnormalities in ≥10% of patients treated with CARVYKTI® (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

In CARTITUDE-4 and CARTITUDE-1 (N=285)[1]

Patients treated with CARVYKTI® may develop secondary malignancies

- 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 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

INCREASED EARLY MORTALITY

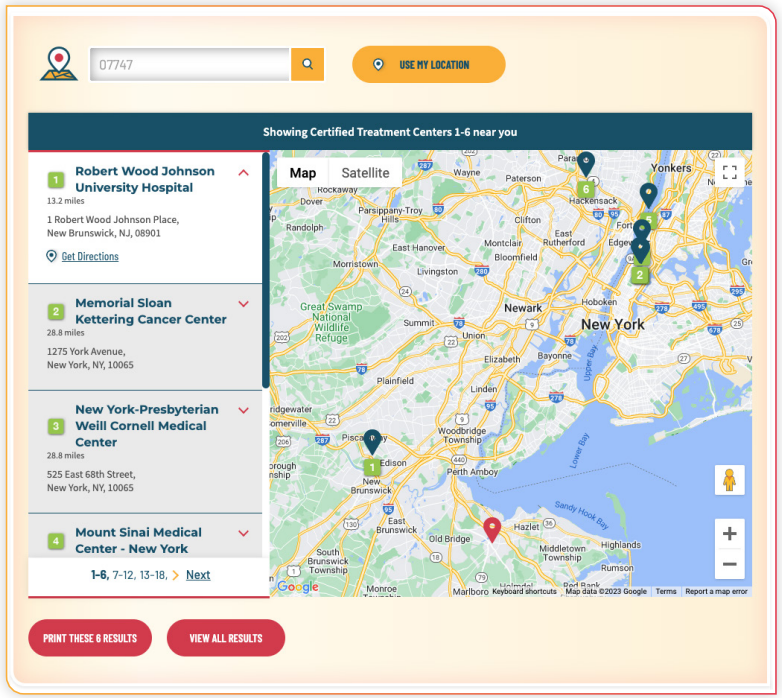
In CARTITUDE-4 (N=208)[1]

- 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 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)
- Inform patients of the risk of early mortality

BCMA=B-cell maturation antigen; CAR=chimeric antigen receptor; CD19=cluster of differentiation 19.

FOR COMMUNITY PHYSICIANS

FIND A CARVYKTI® CERTIFIED TREATMENT CENTER



Scan QR code to find a **CARVYKTI® Certified Treatment Center** near you or visit CARVYKTIHCP.com

Data rates may apply.

FOR CARVYKTI® CERTIFIED TREATMENT CENTERS

ORDER MANAGEMENT AND FULFILLMENT SUPPORT

Full access to online and live support helps CARVYKTI® Certified Treatment Centers manage and fulfill their patients' orders using the following services:

- Cell Therapy Experience Leads (CTELs) to provide training and education
- Order Specialists to address questions, requests, and order status
- CQUENCE® intuitive online portal created to help you manage CARVYKTI® orders

LEARN MORE

Visit **CQUENCEPORTAL.COM**, call **1-833-276-7337** (1-833-CQORDER), or contact your dedicated CTEL

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. 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. CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program. cp-300288v4

CARVYKTI® IS THE #1 PRESCRIBED CAR-T CELL THERAPY FOR RRMM[2]*

Johnson & Johnson and Legend Biotech are committed to reliable and timely delivery of CARVYKTI® to patients

We have delivered

OVER 3000

CARVYKTI® orders since March 2022[1†]

In 2024,

94%‡ OF ORDERS

were available for delivery on or before the projected delivery date[1]

Our widespread network of CARVYKTI® Certified Treatment Centers can book up to 3 months in advance with

NO MONTHLY BOOKING LIMIT

CAR-T=chimeric antigen receptor-T cell; RRMM=relapsed/refractory multiple myeloma.

*From January 2021 to November 2024.

†Commercial product orders delivered since March 2022.

‡January 2024-December 2024 .

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Table of Contents

Give your adult patients with RRMM who have received a PI and an immunomodulatory agent and are lenalidomide-refractory a chance for results that are

POWERFUL. DEEP. DURABLE

After a One-Time Infusion[1-3]

CARTITUDE-4 primary analysis demonstrated*:

POWERFUL

mPFS not reached with CARVYKTI® (95% CI: 22.8-NE) **vs 12 months with standard therapy** (95% CI: 9.8-14)

59% reduction in the risk of disease progression or death vs standard therapy (DPd or PVd)†
(HR=0.41; 95% CI: 0.30-0.56; *P*<0.0001)

DEEP

85% ORR and 74% ≥CR with CARVYKTI® vs 68% ORR and 22% ≥CR with standard therapy

DURABLE

mDOR not reached with CARVYKTI® in patients who achieved PR or better or in patients who achieved CR or better vs 16.6 months with standard therapy

Safety profile

- **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: increased early mortality, prolonged and recurrent cytopenias, infections, hypogammaglobulinemia, hypersensitivity reactions, secondary malignancies, and effects on ability to drive and use machines
- The most common nonlaboratory **adverse reactions** (≥20%) included: 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

NCCN CATEGORY 1

***THE FIRST AND ONLY* CAR-T CELL THERAPY TO BE DESIGNATED AS NCCN CATEGORY 1** in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for multiple myeloma after 1 prior therapy[8‡]

DISCOVER MORE AT CARVYKTIHCP.COM
Data rates may apply.

CAR-T=chimeric antigen receptor-T cell; CI=confidence interval; CR=complete response; DPd=daratumumab, pomalidomide, dexamethasone; HR=hazard ratio; ISS=International Staging System; mDOR=median duration of response; mPFS=median progression-free survival; NCCN=National Comprehensive Cancer Network® (NCCN®); NE=not estimable; ORR=overall response rate; PI=proteasome inhibitor; PR=partial response; PVd=pomalidomide, bortezomib, dexamethasone; RRMM=relapsed or refractory multiple myeloma.

*Median follow-up was 15.9 months in the Intent-to-Treat Analysis Set.

†Based on a stratified Cox proportional hazards model. An HR <1 indicates an advantage for CARVYKTI® arm. For all stratified analyses, stratification was based on investigator's choice (DPd or PVd), ISS staging (I, II, III) and number of prior lines (1 vs 2 or 3) as randomized.

‡Listed under "Therapy for Previously Treated Multiple Myeloma Relapsed/Refractory Disease After 1-3 Prior Therapies" as an option after 1 prior line of therapy, including an immunomodulatory drug (IMID) and a proteasome inhibitor (PI), and refractory to lenalidomide.[8]

References: 1. CARVYKTI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Data on file. Janssen Biotech, Inc. **3.** San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or standard care in lenalidomide-refractory multiple myeloma. *N Engl J Med*. 2023;389(4):335-347. doi:10.1056/NEJMoa2303379 **4.** Dhakal B, Yong K, Harrison S, et al. Phase 3 results from CARTITUDE-4: cilta-cel versus standard of care (PVd or DPd) in lenalidomide-refractory multiple myeloma. Presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL. Virtual presentation. **5.** San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or standard care in lenalidomide-refractory multiple myeloma. Supplement 1. *N Engl J Med*. 2023;389(4):335-347. doi:10.1056/NEJMoa2303379 **6.** Mateos MV, San-Miguel J, Dhakal B, et al. Overall survival with ciltacabtagene autoleucel versus standard of care in lenalidomide-refractory multiple myeloma: phase 3 CARTITUDE-4 study update. Presented at the 21st International Myeloma Society (IMS) Annual Meeting; September 25-28, 2024; Rio de Janeiro, Brazil. Oral Presentation. **7.** 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. doi: 10.1016/S0140-6736(21)00933-8 **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.1.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed January 25, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Johnson&Johnson LEGEND BIOTECH

Please see Important Safety Information throughout and on pages 12-15 and read accompanying full Prescribing Information, including Boxed Warning, for CARVYKTI®.