

Single infusion of CARVYKTI® (ciltacabtagene autoleucel) delivered five-year treatment-free remissions in 50% of patients in early line relapsed/refractory multiple myeloma

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- New results suggest earlier treatment may increase the likelihood of long-term remission
- Study adds to Johnson & Johnson's overwhelming body of evidence supporting its innovative multiple myeloma therapies in second line, where earlier intervention may increase long-term remission and disease control

RARITAN, N.J., Sept. 25, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ), a worldwide leader in multiple myeloma therapies, announced today new long-term follow-up data from the initial subgroup of cohort A in the Phase 2 CARTITUDE-2 study (N=20) showing that 50% of patients (10/20) in early line relapsed or refractory multiple myeloma (RRMM) who were treated with a single infusion of CARVYKTI® (ciltacabtagene autoleucel; ciltacel) remained alive and progression-free for at least five years without maintenance therapy.¹ These results build on the durable, treatment-free remissions observed in the **CARTITUDE-1 study**, which evaluated patients in later lines of therapy, and reinforce that earlier treatment with CARVYKTI® may increase long-term remission and disease control. Together, these findings add to the emerging evidence suggesting that CARVYKTI® may have curative potential in some patients.

Findings were presented at the International Myeloma Society (IMS) Annual Meeting (Abstract #PA-288).

Expert and company perspectives on earlier treatment-free remissions with CARVYKTI®

"Five years ago, treatment-free remissions of this duration were difficult to imagine for many patients with relapsed or refractory multiple myeloma," said Niels van de Donk, M.D., Ph.D., Professor of Hematology, University Medical

Center, Amsterdam, the Netherlands.* "These new CARVYKTI findings provide additional evidence that when highly effective, established therapies are used earlier in the disease course, more patients may have the opportunity to achieve deep, durable remissions and long-term disease control without maintenance."

"These results add to the growing body of evidence suggesting that CARVYKTI may have curative potential for some patients, and reinforce the value of bringing highly effective therapies to patients earlier in their treatment journey," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson. "As we continue to advance a portfolio of complementary and combinable therapies, these findings reinforce our commitment to pursuing curative approaches and redefining what patients can expect from multiple myeloma treatment."

Phase 2 CARTITUDE-2 study build on previous findings

CARTITUDE-2 cohort A (N=20) enrolled patients with RRMM who had received one to three prior lines of therapy, were exposed to a proteasome inhibitor, and were refractory to lenalidomide.¹ The primary endpoint was minimal residual disease (MRD) negativity.¹ Patients from initial cohort A were followed to assess long-term outcomes following a single CARVYKTI® infusion without maintenance therapy.¹

At a median follow-up of 60.7 months:

- Half of the patients (n=10, 50%) remained alive and progression-free at five years
- The five-year overall survival rate was 69.2%
- Median progression-free survival was 60.5 months
- Patients received a single CARVYKTI® infusion without maintenance therapy

At five years, MRD was assessed by bone marrow in three patients and was not required per protocol.¹ All three patients were MRD-negative at the deepest level tested (10^{-6}), indicating no detectable disease using highly sensitive testing methods.¹

Long-term remissions were observed even among patients with high-risk disease features.¹ Of the 10 patients who remained alive and progression-free at five years, five had at least one high-risk cytogenetic abnormality, including four patients with two or more high-risk features.¹

The safety profile observed with longer follow-up was consistent with the known safety profile of CARVYKTI®, with no new CAR T-cell-related neurotoxicity reported.¹ Since the previous analysis, one patient developed a new hematologic malignancy (acute myeloid leukemia) and two deaths occurred due to progressive disease and new cancer.¹

About CARTITUDE-2

CARTITUDE-2 (**NCT04133636**) is an ongoing, multicohort Phase 2 study evaluating the efficacy and safety of ciltacabtagene autoleucel (CARVYKTI®) in patients in different clinical settings, including patients with one to three prior lines of therapy, and continues to generate long-term follow-up data on depth and durability of response. CARTITUDE-2 findings have been presented at major medical congresses, including the International Myeloma Society (IMS) Annual Meeting, and contribute to the growing body of evidence supporting earlier use of CARVYKTI® in multiple myeloma.

About multiple myeloma

Multiple myeloma is a complex blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.² In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.³ Multiple myeloma is the third most common blood cancer worldwide.⁴ More than 180,000 new cases of multiple myeloma are diagnosed globally each year.⁵ People living with multiple myeloma have a 5-year survival rate of 59.8%.⁶ While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels and kidney problems or infections.^{7,8} In recent years, potential overall survival has improved from years to decades for some patients, with effective treatment options now available across every stage and line of therapy.⁹

About Johnson & Johnson's multiple myeloma portfolio

Johnson & Johnson is a global leader in multiple myeloma therapies, with a broad and differentiated portfolio designed to address the complexity and heterogeneity of the disease. Our portfolio spans multiple mechanisms of action, targets and treatment modalities, including CD38-directed therapies, BCMA- and GPRC5D-targeting bispecific antibodies, and cellular therapies.

Over the past decade, Johnson & Johnson therapies have helped extend survival for patients with multiple myeloma. With the right medicines, used as early as possible, combined and sequenced for the best results, Johnson & Johnson is expanding treatment options to match the right therapy to the right patient at the right stage of disease and drive deeper and more durable responses.

Through ongoing research and a robust clinical program, Johnson & Johnson is committed to transforming multiple myeloma into a more manageable condition that is no longer treated to progression but has the potential to, ultimately, be cured.

About CARVYKTI®

CARVYKTI® (cilta-cel) received U.S. Food and Drug Administration approval in February 2022 for the treatment of

adults 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.¹⁰

In April 2024, CARVYKTI® was approved in the U.S. for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor, an immunomodulatory agent, and who are refractory to lenalidomide, following a unanimous (11 to 0) FDA Oncologic Drugs Advisory Committee (ODAC) recommendation in support of this new indication. In April 2024, the European Medicines Agency (EMA) approved a Type II variation for CARVYKTI® for the treatment of adults with relapsed and refractory multiple myeloma who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide. In September 2022, Japan's Ministry of Health, Labour and Welfare (MHLW) approved CARVYKTI® for the treatment of adults with relapsed or refractory multiple myeloma in patients that have no history of CAR-positive T cell infusion therapy targeting BCMA and who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy. In July 2026, CARVYKTI® obtained a label expansion in Japan, allowing its use in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

CARVYKTI® is a BCMA-directed, autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding chimeric antigen receptor (CAR) that directs the CAR-positive T cells to eliminate cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B cells and plasma cells. The CARVYKTI® CAR protein features two BCMA-targeting single domains designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells. CARVYKTI® is available in 17 markets worldwide and has been used to treat more than 13,000 patients globally.

In December 2017, Janssen Biotech, Inc., a Johnson & Johnson company, entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialize CARVYKTI®.

For more information, visit www.CARVYKTI.com.

CARVYKTI® Important Safety Information

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED and RECURRENT CYTOPENIA, and SECONDARY HEMATOLOGICAL MALIGNANCIES Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active

infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids. Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI[®], including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI[®]. Provide supportive care and/or corticosteroids as needed. Parkinsonism and Guillain-Barré syndrome (GBS) and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI[®]. Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI[®]. HLH/MAS can occur with CRS or neurologic toxicities. Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI[®]. Immune Effector Cell-associated Enterocolitis (IEC-EC), including fatal or life threatening reactions, occurred following treatment with CARVYKTI[®]. Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI[®]. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI[®].

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 $\geq$ 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 ($\geq 10\%$) included fever (84%),

hypotension (29%) and aspartate aminotransferase increased (11%). Serious events that may be associated with CRS include pyrexia, hemophagocytic lymphohistiocytosis, respiratory failure, disseminated intravascular coagulation, capillary leak syndrome, and supraventricular and ventricular tachycardia. CRS occurred in 78% of patients in CARTITUDE-4 (3% Grade 3 to 4) and in 95% of patients in CARTITUDE-1 (4% Grade 3 to 4).

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

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

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

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

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

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

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

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS): Patients receiving CARVYKTI® may experience

fatal or life-threatening ICANS following treatment with CARVYKTI[®], including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS.

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

Immune Effector Cell-associated Neurotoxicity Syndrome occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3) and in 23% of patients in CARTITUDE-1 (3% Grade 3). The most frequent ($\geq 2\%$) manifestations of ICANS included encephalopathy (12%), aphasia (4%), headache (3%), motor dysfunction (3%), ataxia (2%), and sleep disorder (2%). Monitor patients at least daily for 7 days following CARVYKTI[®] infusion for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms.

Monitor patients for signs or symptoms of ICANS for at least 2 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed. Advise patients to avoid driving for at least 2 weeks following infusion.

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

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

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

Guillain-Barré syndrome: A fatal outcome following GBS occurred following treatment with CARVYKTI[®] despite

treatment with intravenous immunoglobulins. Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances, and polyradiculoneuritis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Hypogammaglobulinemia can occur in patients receiving treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & -4 studies, hypogammaglobulinemia adverse event was reported in 36% (102/285) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 93% (265/285) of patients. Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion occurred in 94% (267/285) of patients treated. Fifty-six percent (161/285) of patients received intravenous immunoglobulin (IVIG) post CARVYKTI® for either an adverse reaction or prophylaxis. Monitor immunoglobulin levels after treatment with CARVYKTI® and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at <https://www.jnj.com/> or at www.jnj.com/innovativemedicine/ Follow us at @JNJInnovMed. Janssen Research & Development, LLC, and Janssen Biotech, Inc., are both Johnson & Johnson companies.

Caution Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development of CARVYKTI® (ciltacabtagene autoleucel; cilta-cel). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory actions; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnote

* Niels van de Donk, MD, PhD, Professor of Hematology, University Medical Center, Amsterdam, Netherlands, has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

- ¹ Cohen A, et al. Long-Term (≥5-Year) Remission and Survival With Ciltacabtagene Autoleucel (Cilta-Cel) in Relapsed/Refractory Multiple Myeloma (RRMM) With 1 to 3 Prior Lines of Therapy: CARTITUDE-2 Cohort A. Presented at: The 2026 International Myeloma Society (IMS) Annual Meeting; September 25, 2026; Glasgow, Sweden.
- ² Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. Am J Hematol. 2020;95(5):548-567.
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