



**News Release**

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**Longer-term Data from CARTITUDE-1 Study Demonstrate Continued Deep and Durable Responses to CARVYKTI™ (ciltacabtagene autoleucel) in Heavily Pretreated Patients with Relapsed or Refractory Multiple Myeloma**

*At nearly 28 months of median follow-up, median progression-free survival and overall survival were not yet reached*

*Data presented at the 2022 ASCO Annual Meeting and published in the Journal of Clinical Oncology*

**June 4, 2022 (CHICAGO)** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today updated results from the Phase 1b/2 CARTITUDE-1 study evaluating the efficacy and safety of CARVYKTI™ (ciltacabtagene autoleucel; cilta-cel), a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy. The study included patients with relapsed or refractory multiple myeloma (RRMM) who had received  $\geq 3$  lines of therapy including a proteasome inhibitor (PI), an anti-CD38 monoclonal antibody and an immunomodulatory agent (IMiD) or were double refractory to an IMiD and PI and who had received a PI, an IMiD and an anti-CD38 as part of previous

therapy. A median overall survival (OS) of 9.3 months has been reported in refractory patients who were triple-class exposed.<sup>1</sup> These data, featured as a poster presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting ([Abstract #8028](#)), were simultaneously published in the [Journal of Clinical Oncology](#).

The poster results showed that at a median follow-up of 28 months, in 97 patients treated with CARVYKTI™, the overall response rate (ORR) remained consistent at 98 percent (95 percent Confidence Interval [CI], 92.7 to 99.7), with 83 percent (95 percent CI, 73.4 to 89.4) of patients treated with CARVYKTI™ achieving a stringent complete response (sCR).<sup>2</sup> The responses were durable, and median OS and progression free survival (PFS) were not reached. PFS and OS rates at 28 months follow-up were 55 percent (95 percent CI, 44.0 to 64.6) and 70 percent (95 percent CI, 60.1 to 78.6), respectively.<sup>2</sup>

Sixty-one patients had samples evaluable for minimal residual disease (MRD) status, 92 percent of whom achieved MRD negativity at the 10<sup>-5</sup> threshold, which was sustained for ≥6 months in 68 percent (34/50 with sufficient follow-up) and ≥12 months in 55 percent (24/44 with sufficient follow-up).<sup>2</sup> In those same patients, two-year PFS rates were 73 percent (95 percent CI, 52.1 to 85.9) and 79 percent (95 percent CI, 51.5 to 91.8), respectively, and two-year OS rates were 94 percent (95 percent CI, 76.1 to 98.3) and 91 percent (95 percent CI, 67.7 to 97.6), respectively.<sup>2</sup> Both the two-year PFS and OS rates were favorable compared to the overall study population.<sup>2</sup>

“The latest results from the CARTITUDE-1 study further reinforce the potential of cilta-cel as an important treatment option for patients with a high unmet need who otherwise face a poor prognosis,” said Saad Z. Usmani, M.D., M.B.A., F.A.C.P., Chief of the Myeloma Service at Memorial Sloan Kettering Cancer Center and study investigator.<sup>‡</sup> “The response rates observed in the two-year follow-up, with median PFS not reached and the majority of patients achieving MRD negativity, demonstrate that cilta-cel provides the potential for long-term disease control and survival in heavily pretreated patients with relapsed or refractory multiple myeloma.”

The study included patients (n=97) who received a median of six prior treatment regimens (range, 3-18).<sup>2</sup> All patients were triple-class [IMiD, PI and anti-CD38 antibody] exposed, while 42 percent of patients were penta-drug refractory and 99 percent of patients were refractory to the last line of therapy.<sup>2</sup>

No new safety signals were observed with longer follow-up.<sup>2</sup> The most common hematologic adverse events (AEs) observed were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (54 percent).<sup>3</sup> Since the primary 12-month publication, no new events or changes in incidence rate, time to onset, or duration of cytokine release syndrome (CRS) occurred, and one new case of treatment-related Parkinsonism, or movement and neurocognitive treatment (MNT) emergent adverse event occurred.<sup>2</sup>

### **CARVYKTI™ Results in Earlier Lines of Treatment**

Findings from Cohort B (n=19) of the Phase 2 CARTITUDE-2 ([NCT04133636](#)) study, evaluating the safety and efficacy of cilta-cel in patients with RRMM who received one prior line of therapy including a PI and IMiD and had disease progression within 12 months of treatment with autologous stem cell transplant (ASCT) or within 12 months of the start of antineoplastic therapy for patients who have not had ASCT, showed patients treated with cilta-cel experienced early and deep responses at a median follow-up of 13-months.<sup>4</sup> In 19 patients treated in this cohort, the ORR was 100 percent (95 percent CI, 82.4 to 100), with 90 percent (95 percent CI, 66.9 to 98.7) of patients achieving a CR or better and 95 percent (95 percent CI, 74.0 to 99.9) of patients achieving a very good partial response (VGPR) or better.<sup>4</sup> Median time to first response was 1 month (range, 0.9-9.7).<sup>4</sup> The 12-month PFS rate was 90 percent.<sup>4</sup> The overall safety profile, including incidence of CRS and most common hematologic AEs, was consistent with observations in the CARTITUDE-1 study.<sup>4</sup> These data were presented for the first time at ASCO ([Abstract #8029](#)) and will be featured as an oral presentation at the European Hematology Association (EHA) 2022 Congress ([Abstract #S185](#)).<sup>4,5</sup>

Updated results from Cohort A (n=20) of the CARTITUDE-2 study evaluating cilta-cel safety and efficacy in multiple myeloma patients who are lenalidomide refractory with 1–3 prior

lines of treatment were also presented as a poster presentation at ASCO 2022 ([Abstract #8020](#)).<sup>6</sup>

“We are pleased to see the clinical benefit of CARVYKTI as demonstrated in these results from CARTITUDE-1 that show deep and durable responses were maintained over time,” said Sen Zhuang M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. “As part of our dedication to advance the science of multiple myeloma, we remain committed to further investigating the potential of CARVYKTI in earlier lines of treatment, including in the CARTITUDE-2 study as part of the CARVYKTI clinical development program.”

CARVYKTI™ [received](#) approval by the U.S. FDA 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. CARVYKTI™ is not currently approved in any other treatment setting.

On May 25, 2022, CARVYKTI™ was [granted](#) conditional marketing authorization by the European Medicines Agency (EMA) for the treatment of adults with RRMM who have received at least three prior therapies, including a PI, an IMiD and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.

### **About CARVYKTI™ (ciltacabtagene autoleucel)**

CARVYKTI™ is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient’s own T cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates 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 domain antibodies 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.<sup>7</sup>

In December 2017, Janssen Biotech, Inc. [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](http://www.CARVYKTI.com).

### **About the CARTITUDE-1 Study**

CARTITUDE-1 ([NCT03548207](#)) is an ongoing Phase 1b/2, open-label, multi-center study evaluating ciltacabtagene autoleucel for the treatment of patients with relapsed or refractory multiple myeloma, who previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 monoclonal antibody, and who had disease progression on or after the last regimen. Patients in the study had received a median of six prior treatment regimens (range, 3-18). Of the 97 patients enrolled in the trial, 99 percent were refractory to the last line of treatment and 88 percent were triple-class refractory, meaning their cancer did not respond to, or had progressed on, an IMiD, a PI and an anti-CD38 monoclonal antibody.<sup>2</sup>

### **About the CARTITUDE-2 Study**

CARTITUDE-2 ([NCT04133636](#)) is an ongoing, multi-cohort Phase 2 study evaluating the safety and efficacy of cilta-cel in patients with multiple myeloma. Cohort B evaluates patients who received one line of prior therapy including a PI and an IMiD, and had disease progression per IMWG criteria within 12 months after treatment with autologous stem cell transplantation (ASCT) or from the start of anti-myeloma therapy for participants who have not had an ASCT. Cohort A evaluates patients who had progressive multiple myeloma after 1–3 prior lines of therapy including a PI and an IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents.

### **About Multiple Myeloma**

Multiple myeloma is an incurable blood cancer that affects some white blood cells called plasma cells, which are found in the bone marrow.<sup>8</sup> When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. In 2020, worldwide an estimated 176,000 people were diagnosed with multiple myeloma.<sup>9</sup> In 2022,

it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.<sup>10</sup> 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, kidney problems or infections.<sup>8</sup>

## **CARVYKTI™ Important Safety Information**

### **INDICATIONS AND USAGE**

CARVYKTI™ (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

### **WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, and PROLONGED and RECURRENT CYTOPENIA**

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

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

**Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI™.**

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

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

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

## **WARNINGS AND PRECAUTIONS**

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

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

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

Monitor patients at least daily for 10 days following CARVYKTI™ infusion at a REMS-certified healthcare facility for signs and symptoms of CRS. Monitor patients for signs or

symptoms of CRS for at least 4 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

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

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

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

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

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

**Parkinsonism:** Of the 25 patients in the CARTITUDE-1 study experiencing any neurotoxicity, five male patients had neurologic toxicity with several signs and symptoms



of parkinsonism, distinct from immune effector cell-associated neurotoxicity syndrome (ICANS). Neurologic toxicity with parkinsonism has been reported in other ongoing trials of ciltacabtagene autoleucel. Patients had parkinsonian and non-parkinsonian symptoms that included tremor, bradykinesia, involuntary movements, stereotypy, loss of spontaneous movements, masked facies, apathy, flat affect, fatigue, rigidity, psychomotor retardation, micrographia, dysgraphia, apraxia, lethargy, confusion, somnolence, loss of consciousness, delayed reflexes, hyperreflexia, memory loss, difficulty swallowing, bowel incontinence, falls, stooped posture, shuffling gait, muscle weakness and wasting, motor dysfunction, motor and sensory loss, akinetic mutism, and frontal lobe release signs. The median onset of parkinsonism in the 5 patients in CARTITUDE-1 was 43 days (range 15-108) from infusion of ciltacabtagene autoleucel.

Monitor patients for signs and symptoms of parkinsonism that may be delayed in onset and managed with supportive care measures. There is limited efficacy information with medications used for the treatment of Parkinson's disease, for the improvement or resolution of parkinsonism symptoms following CARVYKTI™ treatment.

Guillain-Barré Syndrome: A fatal outcome following Guillain-Barré Syndrome (GBS) has occurred in another ongoing study of ciltacabtagene autoleucel despite treatment with intravenous 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.

Peripheral Neuropathy: Six patients in CARTITUDE-1 developed peripheral neuropathy. These neuropathies presented as sensory, motor or sensorimotor neuropathies. Median time of onset of symptoms was 62 days (range 4-136 days), median duration of peripheral neuropathies was 256 days (range 2-465 days) including those with ongoing neuropathy. Patients who experienced peripheral neuropathy also experienced cranial nerve palsies or GBS in other ongoing trials of ciltacabtagene autoleucel.

Cranial Nerve Palsies: Three patients (3.1%) experienced cranial nerve palsies in CARTITUDE-1. All three patients had 7th cranial nerve palsy; one patient had 5th cranial nerve palsy as well. Median time to onset was 26 days (range 21-101 days) following infusion of ciltacabtagene autoleucel. Occurrence of 3rd and 6th cranial nerve palsy, bilateral 7th cranial nerve palsy, worsening of cranial nerve palsy after improvement, and occurrence of peripheral neuropathy in patients with cranial nerve palsy have also been reported in ongoing trials of ciltacabtagene autoleucel. Monitor patients for signs and symptoms of cranial nerve palsies. Consider management with systemic corticosteroids, depending on the severity and progression of signs and symptoms.

**Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS):** Fatal HLH occurred in one patient (1%), 99 days after ciltacabtagene autoleucel. The HLH event was preceded by prolonged CRS lasting 97 days. The manifestations of HLH/MAS include hypotension, hypoxia with diffuse alveolar damage, coagulopathy, cytopenia, and multi-organ dysfunction, including renal dysfunction. 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 [www.CARVYKTIrems.com](http://www.CARVYKTIrems.com) or 1-844-672-0067.

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

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

Recurrent Grade 3 or 4 neutropenia, thrombocytopenia, lymphopenia and anemia were seen in 63% (61/97), 18% (17/97), 60% (58/97), and 37% (36/97) after recovery from initial Grade 3 or 4 cytopenia following infusion. After Day 60 following ciltacabtagene autoleucel infusion, 31%, 12% and 6% of patients had a recurrence of Grade 3 or higher lymphopenia, neutropenia and thrombocytopenia, respectively, after initial recovery of their Grade 3 or 4 cytopenia. Eighty-seven percent (84/97) of patients had one, two, or three or more recurrences of Grade 3 or 4 cytopenias after initial recovery of Grade 3 or 4 cytopenia. Six and 11 patients had Grade 3 or 4 neutropenia and thrombocytopenia, respectively, at the time of death.

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

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

Infections (all grades) occurred in 57 (59%) patients. Grade 3 or 4 infections occurred in 23% (22/97) of patients; Grade 3 or 4 infections with an unspecified pathogen occurred in 17%, viral infections in 7%, bacterial infections in 1%, and fungal infections in 1% of patients. Overall, four patients had Grade 5 infections: lung abscess (n=1), sepsis (n=2) and pneumonia (n=1).

Monitor patients for signs and symptoms of infection before and after CARVYKTI™ infusion and treat patients appropriately. Administer prophylactic, pre-emptive and/or therapeutic antimicrobials according to the standard institutional guidelines. Febrile neutropenia was observed in 10% of patients after ciltacabtagene autoleucel infusion, and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids and other supportive care, as medically indicated.

**Viral Reactivation:** Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients with

hypogammaglobulinemia. Perform screening for Cytomegalovirus (CMV), HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV), or any other infectious agents if clinically indicated in accordance with clinical guidelines before collection of cells for manufacturing. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

**Hypogammaglobulinemia** was reported as an adverse event in 12% (12/97) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 92% (89/97) of patients. Monitor immunoglobulin levels after treatment with CARVYKTI™ and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

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

**Hypersensitivity Reactions** have occurred in 5% (5/97) of patients following ciltacabtagene autoleucel infusion. Serious hypersensitivity reactions, including anaphylaxis, may be due to the dimethyl sulfoxide (DMSO) in CARVYKTI™. Patients should be carefully monitored for 2 hours after infusion for signs and symptoms of severe reaction. Treat promptly and manage appropriately according to the severity of the hypersensitivity reaction.

**Secondary Malignancies:** Patients may develop secondary malignancies. 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 for testing of secondary malignancy of T cell origin.

**Effects on Ability to Drive and Use Machines:** Due to the potential for neurologic events, including altered mental status, seizures, neurocognitive decline, or neuropathy, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following CARVYKTI™ infusion. Advise patients to refrain from driving and engaging in

hazardous occupations or activities, such as operating heavy or potentially dangerous machinery during this initial period, and in the event of new onset of any neurologic toxicities.

## **ADVERSE REACTIONS**

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

Please read full [Prescribing Information](#) including Boxed Warning for CARVYKTI™.

## **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism, & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [@JanssenGlobal](#) and [@JanssenUS](#). Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Pharmaceutica NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*\*Saad Z. Usmani, M.D., M.B.A., F.A.C.P. has provided consulting, advisory, and speaking services to Janssen; he has not been paid for any media work.*

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## **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development 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 Janssen Biotech, Inc., Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies, and/or 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 action; 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 Annual Report on Form 10-K for the fiscal year ended January 2, 2022, 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](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of Janssen Biotech, Inc., Janssen Research & Development, LLC, the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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<sup>1</sup> Gandhi UH, Cornell RF, Lakshman A, et al. Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. *Leukemia* 2019; 33: 2266–75.

<sup>2</sup> Usmani, S. Phase 1b/2 study of ciltacabtagene autoleucel, a BCMA-directed CAR-T cell therapy, in patients with relapsed/refractory multiple myeloma (CARTITUDE-1): Two years post-LPI. Abstract #8028 [Poster]. Presented at the 2022 American Society of Clinical Oncology Annual Meeting.

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- <sup>3</sup> Martin, Thomas et al. Ciltacabtagene Autoleucl, an Anti-B-cell Maturation Antigen Chimeric Antigen Receptor T-Cell Therapy, for Relapsed/Refractory Multiple Myeloma: CARTITUDE-1 2 Years Post Last-Patient-In. *Journal of Clinical Oncology*. doi: JCO.22.00842R1. In press.
- <sup>4</sup> van de Donk, N et al. Biological correlative analyses and updated clinical data of ciltacabtagene autoleucl (cilta-cel), a BCMA-directed CAR-T cell therapy, in patients with multiple myeloma (MM) and early relapse after initial therapy: CARTITUDE-2, cohort B. Abstract #8029 [Poster]. Presented at the 2022 American Society of Clinical Oncology Annual Meeting.
- <sup>5</sup> van de Donk, N et al. Biological correlative analyses and updated clinical data of ciltacabtagene autoleucl (cilta-cel), a BCMA-directed CAR-T cell therapy, in patients with multiple myeloma (MM) and early relapse after initial therapy: CARTITUDE-2, cohort B. Abstract #S185 [Oral]. To be presented at the 2022 European Hematology Association Congress.
- <sup>6</sup> Einsele, Hermann et al. Biological Correlative Analyses and Updated Clinical Data of Ciltacabtagene Autoleucl, a BCMA-Directed CAR-T Cell Therapy, in Lenalidomide-Refractory Patients With Progressive Multiple Myeloma After 1–3 Prior Lines of Therapy: CARTITUDE-2, Cohort A. Abstract #8020 [Poster]. Presented at the 2022 American Society of Clinical Oncology Annual Meeting.
- <sup>7</sup> CARVYKTI™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
- <sup>8</sup> American Cancer Society. "What Is Multiple Myeloma?" Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html>. Accessed May 2022.
- <sup>9</sup> Multiple myeloma - statistics. Cancer.Net. Available at: <https://www.cancer.net/cancer-types/multiple-myeloma/statistics#:~:text=Worldwide%2C%20an%20estimated%20176%2C404%20people,worldwide%20died%20from%20multiple%20myeloma>. Published March 31, 2022. Accessed June 3, 2022.
- <sup>10</sup> American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society's%20estimates,men%20and%205%2C570%20in%20women>. Accessed May 2022.