

For Immediate Release

## Treatment with CARVYKTI® (ciltacabtagene autoleucel) Resulted in Clinically Meaningful Improvements in Health-Related Quality of Life and Reductions in Disease-Specific Symptoms in Patients with Earlier-Line Multiple Myeloma

*Oral presentations at the 2023 ASH Annual Meeting include patient-reported outcomes from the CARTITUDE-4 study and longer-term efficacy and safety data from CARTITUDE-2 study cohorts A and B, show the promise of CARVYKTI® in earlier lines of treatment*

**SAN DIEGO, December 11, 2023** – Johnson & Johnson announced today new patient-reported outcomes (PRO) from the Phase 3 CARTITUDE-4 study of CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) demonstrated clinically meaningful improvements in health-related quality of life and meaningful reductions in disease-specific symptoms according to multiple PRO measures in the treatment of adult patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy (LOT). These data were featured as an oral presentation at the 2023 American Society of Hematology (ASH) Annual Meeting ([Abstract #1063](#)).<sup>1</sup>

“These results from the CARTITUDE-4 study showed the potential of cilta-cel to significantly improve health-related quality of life measures for patients, including pain, fatigue and emotional functioning,” said Roberto Mina, Assistant Professor, Division of Hematology, Department of Molecular Biotechnology and Health Sciences, University of Torino, Turin, Italy.<sup>‡</sup> “Cilta-cel has demonstrated deep and durable responses in later lines of therapy, and these results show the potential of cilta-cel for patients with lenalidomide-refractory multiple myeloma as early as after first relapse.”

In this analysis of the Phase 3 CARTITUDE-4 study, patients in the CARVYKTI® arm reported improved functioning and symptom reduction from baseline, while PRO scores in the standard of care (SOC) regimens, pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd) arm trended toward worsening or lower degrees of improvement from baseline for most domains and symptoms.<sup>Error! Bookmark not defined.</sup> CARVYKTI® exceeded clinically meaningful thresholds for average improvement in global health status (10.1 points), pain (–10.2 points) and the visual analogue scale (8.0 points) from baseline to month 12; improvements in fatigue (–9.1 points) and emotional functioning (9.5 points) neared clinically meaningful thresholds.<sup>1</sup> Using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30; 100-point scale), a 30-item instrument designed to measure quality of life in all cancer patients, the analysis showed that results numerically favored CARVYKTI® for all other domains.<sup>Error! Bookmark not defined.</sup><sup>2</sup> The median time until multiple myeloma symptom worsening in the CARVYKTI® arm was 23.7 months compared to 18.9 months in the SOC arm (Hazard Ratio [HR]= 0.42; 95 percent Confidence Interval [CI], 0.26–0.68; p value p0.003), measured with the Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q; 5-point scale).<sup>Error! Bookmark not defined.</sup>

The CARTITUDE-4 study enrolled 419 patients with lenalidomide-refractory multiple myeloma and one to three prior LOT.<sup>1</sup> At clinical cut-off, 99 patients in the CARVYKTI® arm and 66 in the SOC arm had both baseline and 12-month PRO assessments, representing data prior to progression.<sup>1</sup> PRO compliance was 100 percent at baseline and decreased with subsequent visits to 74 percent in the CARVYKTI® and 81 percent in the SOC arm at month 12.<sup>Error! Bookmark not defined.</sup> Patients were administered EORTC QLQ-C30, EuroQoL 5-Dimension 5-Level (EQ-5D-5L; 100-point scale) and MySIm-Q questionnaires throughout the course of the study.<sup>1</sup> In the primary analysis of CARTITUDE-4 [presented](#) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, CARVYKTI® reduced the risk of disease progression or death by 74 percent (Hazard Ratio [HR]=0.26; 95 percent Confidence Interval [CI], 0.18–0.38; p value p<0.0001) compared to two SOC regimens, PVd or DPd, in adults with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior LOT.<sup>3</sup>

### CARTITUDE-2: Updated CARVYKTI® Results in Earlier Lines of Treatment

Longer-term efficacy and safety data from CARTITUDE-2 cohorts A and B were also presented in an oral presentation at ASH ([Abstract #1021](#)). At a median follow-up of approximately 29 months, patients treated with CARVYKTI® in earlier LOT, both those with lenalidomide-refractory multiple myeloma after one to three LOT (cohort A) and those with early relapse (cohort B), experienced deep and durable responses.<sup>4</sup> In the 20 patients in cohort A and 19 in cohort B, treatment with CARVYKTI® resulted in overall response rates of 95 percent (complete response or better [≥CR], 90 percent) and 100 percent (≥CR, 90 percent), respectively. Median progression-free survival (PFS) was not reached in either cohort, and 24-

month PFS rates were 75 percent in cohort A and 73 percent in cohort B; respective 24-month overall survival rates were 75 percent and 84 percent.

No new CAR-T-related safety signals were observed; one additional CAR-T cell neurotoxicity of sensory loss (grade 2) which resolved was reported in cohort B.<sup>4</sup> Cohort A provides insight into potential longer-term survival outcomes that may be expected in the Phase 3 CARTITUDE-4 study, which enrolled the same patient population.

“The data presented at ASH highlight our commitment to pursue the development of cutting-edge therapies with the intent of providing clinically meaningful real-life benefits for patients, in addition to robust efficacy and safety data,” said Jordan Schechter, M.D., Vice President, Clinical Development Cellular Therapy Program, Johnson & Johnson Innovative Medicine. “These analyses add to the continued evidence from the CARTITUDE-4 study and build our confidence in the profile of CARVYKTI as a potential and promising treatment option for patients with multiple myeloma whose disease recurs early.”

## About CARTITUDE-4

CARTITUDE-4 ([NCT04181827](#)) is the first international, randomized, open-label Phase 3 study evaluating the efficacy and safety of cilta-cel versus pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd) in adult patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy.

## About CARTITUDE-2

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 proteasome inhibitor (PI) and an immunomodulatory agent (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 CARVYKTI® (ciltacabtagene autoleucel; cilta-cel)

CARVYKTI® 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 PI, an IMiD agent, and an anti-CD38 monoclonal antibody.<sup>5</sup> In May 2022, the European Commission granted [conditional marketing authorization](#) of CARVYKTI® for the treatment of adults with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an IMiD agent, a PI and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.

CARVYKTI® is a BCMA-directed, genetically modified 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.

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 multiple myeloma

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.<sup>6</sup> In multiple myeloma, these plasma cells change, spread rapidly and replace normal cells in the bone marrow with tumors.<sup>7</sup> Multiple myeloma is the third most common blood cancer and remains an incurable disease.<sup>8,9</sup> In 2023, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people will die from the disease.<sup>10</sup> People living with multiple myeloma have a 5-year relative survival rate of 59.8 percent.<sup>11</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 and kidney problems or infections.<sup>12,13</sup>

## CARVYKTI® IMPORTANT SAFETY INFORMATION

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

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

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

Monitor patients at least daily for 10 days following CARVYKTI® infusion at a REMS-certified healthcare facility for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 4 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

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

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

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

**Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS):** Patients may experience fatal or life-threatening ICANS following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. ICANS occurred in 23% (22/97) of patients receiving ciltacabtagene autoleucl including Grade 3 or 4 events in 3% (3/97) and Grade 5 (fatal) events in 2% (2/97). The median time to onset of ICANS was 8 days (range 1-28 days). All 22 patients with ICANS had CRS. The most frequent (≥5%) manifestation of ICANS included encephalopathy (23%), aphasia (8%) and headache (6%).

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

**Parkinsonism:** Of the 25 patients in the CARTITUDE-1 study experiencing any neurotoxicity, 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 autoleucl. 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 autoleucl.

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 autoleucl despite treatment with intravenous immunoglobulin (IVIg). Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances and polyradiculoneuritis.

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

**Immune Mediated Myelitis:** Grade 3 myelitis has occurred 25 days following treatment in another ongoing study. Symptoms reported included hypoesthesia of the lower extremities and the lower abdomen with impaired sphincter control. Symptoms improved with the use of corticosteroids and intravenous immunoglobulin. Myelitis was ongoing at the time of death from other cause.

**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 autoleucl. Monitor patients for signs and symptoms of peripheral neuropathies.

**Cranial Nerve Palsies:** Three patients (3.1%) experienced cranial nerve palsies in CARTITUDE-1. All three patients had 7<sup>th</sup> cranial nerve palsy; one patient had 5<sup>th</sup> cranial nerve palsy as well. Median time to onset was 26 days (range 21-101 days) following infusion of ciltacabtagene autoleucl. Occurrence of 3<sup>rd</sup> and 6<sup>th</sup> cranial nerve palsy, bilateral 7<sup>th</sup> 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 autoleucl. 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 autoleucl. The HLH event was preceded by prolonged CRS lasting 97 days. The manifestations of HLH/MAS include hypotension, hypoxia with diffuse alveolar damage, coagulopathy, cytopenia, and multi-organ dysfunction, including renal dysfunction.

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

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

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

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

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

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

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

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

In a randomized controlled study of relapsed or refractory multiple myeloma (CARTITUDE-4), patients treated with ciltacabtagene autoleucl had an increased rate of fatal COVID-19 infections compared to the standard therapy arm. Counsel patients on the importance of prevention measures. Follow institutional guidelines for the vaccination and management of immunocompromised patients with COVID-19.

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

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

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

**Hypersensitivity Reactions** have occurred in 5% (5/97) of patients following ciltacabtagene autoleucl 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](tel: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 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.janssen.com/johnson-johnson-innovative-medicine](http://www.janssen.com/johnson-johnson-innovative-medicine). Follow us at [@JanssenUS](#) and [@JNJInnovMed](#). Janssen Research & Development, LLC and Janssen Biotech, Inc. are both Johnson & Johnson companies.

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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 product development and the potential benefits and treatment impact of CARVYKTI® (ciltacabtagene autoleucl). 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., 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 1, 2023, 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 Research & Development, LLC, Janssen Biotech, Inc., nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.*

<sup>‡</sup> Dr. Roberto Mina has provided consulting, advisory, and speaking services to Janssen; he has not been paid for any media work.

<sup>1</sup> Mina, R. Patient-Reported Outcomes in the Phase 3 CARTITUDE-4 Study of Ciltacabtagene Autoleucl Vs Standard of Care in Patients with Lenalidomide-Refractory Multiple Myeloma after 1-3 Lines of Therapy. Abstract #1063 [Oral Presentation]. Presented at the 2023 American Society of Hematology Annual Meeting.

<sup>2</sup> European Organisation for Research and Treatment of Cancer (EORTC). "Quality of Life Questionnaires." Accessed November 2023. <https://qol.eortc.org/questionnaires/>

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- <sup>3</sup> Dhakal, B. First phase 3 results from CARTITUDE-4: Cilta-cel versus standard of care (PvD or DPd) in lenalidomide-refractory multiple myeloma. Abstract #LBA106 [Oral Presentation]. Presented at the 2023 American Society of Clinical Oncology Annual Meeting.
- <sup>4</sup> Hillengass, J. The Phase 2 CARTITUDE-2 Trial: Updated Efficacy and Safety of Cilta-cel in Patients with Multiple Myeloma and 1-3 Prior Lines of Therapy (Cohort A) and with Early Relapse after First Line Treatment (Cohort B). Abstract #1021 [Oral Presentation]. Presented at the 2023 American Society of Hematology Annual Meeting.
- <sup>5</sup> CARVYKT<sup>®</sup> Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
- <sup>6</sup> Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. *Am J Hematol*. 2020;95(5):548-567. <http://www.ncbi.nlm.nih.gov/pubmed/32212178>
- <sup>7</sup> National Cancer Institute. Plasma Cell Neoplasms. Accessed October 19, 2023. Available at: <https://www.cancer.gov/types/myeloma/patient/myeloma-treatment-pdq>
- <sup>8</sup> Multiple myeloma. City of Hope, 2022. Multiple Myeloma: Causes, Symptoms & Treatments. Accessed October 19, 2023. <https://www.cancercenter.com/cancer-types/multiple-myeloma>
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- <sup>13</sup> American Cancer Society. Multiple Myeloma Early Detection, Diagnosis, and Staging. Accessed October 19, 2023. Available at: <https://www.cancer.org/cancer/types/multiple-myeloma/detection-diagnosis-staging/detection.html>