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**U.S. FDA Approves CARVYKTI™ (ciltacabtagene autoleucel), Janssen’s First Cell Therapy, a BCMA-Directed CAR-T Immunotherapy for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma**

*In the pivotal clinical study, 98 percent of patients with relapsed or refractory multiple myeloma responded to a one-time treatment with ciltacabtagene autoleucel and 78 percent of patients who responded experienced a stringent complete response*

**HORSHAM, Pa., February 28, 2022** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the U.S. Food and Drug Administration (FDA) has approved CARVYKTI™ (ciltacabtagene autoleucel; cilta-cel) for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.<sup>1</sup> The approval is based on data from the pivotal CARTITUDE-1 study, which included patients who had received a median of six prior treatment regimens (range, 3-18), and had previously received a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.<sup>1</sup> In December 2017, Janssen entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialize ciltacabtagene autoleucel.

CARVYKTI™ is a chimeric antigen receptor T-cell (CAR-T) therapy featuring two B-cell maturation antigen (BCMA)-targeting single domain antibodies.<sup>1</sup> In the pivotal CARTITUDE-1 study, one-time treatment with ciltacabtagene autoleucl resulted in deep and durable responses, with 98 percent (95 percent Confidence Interval [CI], 92.7-99.7) of patients with RRMM responding to therapy (98 percent overall response rate [ORR] (n=97).<sup>1</sup> Notably, 78 percent (95 percent CI, 68.8-86.1) of the patients achieving this level of response (n=76) experienced a stringent complete response (sCR), a measure in which a physician is unable to observe any signs or symptoms of disease via imaging or other tests after treatment.<sup>1</sup> At a median of 18 months follow-up, median duration of response (DOR) was 21.8 months.<sup>1</sup>

CARVYKTI™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI™ REMS Program.<sup>1</sup> The Safety Information for CARVYKTI™ includes a Boxed Warning regarding Cytokine Release Syndrome (CRS), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), Parkinsonism and Guillain-Barré syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), and prolonged and/or recurrent cytopenias.<sup>1</sup> Warnings and Precautions include prolonged and recurrent cytopenias, infections, hypogammaglobulinemia, hypersensitivity reactions, secondary malignancies, and effects on ability to drive and use machines.<sup>1</sup> The most common adverse reactions (≥20 percent) are pyrexia, CRS, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogens unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting.<sup>1</sup>

“We are committed to harnessing our science, deep disease understanding and capabilities to bring forward cell therapies like CARVYKTI as we continue to focus on our ultimate goal of delivering a cure for multiple myeloma,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “We extend our sincere gratitude to the patients, their families and the teams of researchers and study

centers who have participated in the clinical study of CARVYKTI and enabled today's approval."

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>2</sup> Despite the development of additional treatment options in recent years, most people living with multiple myeloma face poor prognoses after experiencing disease progression following treatment with three major therapy classes, which include an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.<sup>3</sup>

"The responses in the CARTITUDE-1 study showed durability over time and resulted in the majority of heavily pretreated patients achieving deep responses after 18-month follow-up," said Sundar Jagannath, M.D.<sup>†</sup>, Director of the Center of Excellence for Multiple Myeloma and Professor of Medicine, Hematology and Medical Oncology, at The Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai, and principal study investigator. "The approval of cilta-cel provides physicians an immunotherapy treatment option that offers patients an opportunity to be free from anti-myeloma therapies for a period of time."

As a personalized medicine, CARVYKTI™ treatment requires extensive training, preparation, and certification to ensure a positive experience for patients. Through a phased approach, Janssen and Legend Biotech will activate a limited network of certified treatment centers as the company works to scale its production capacity and increase the availability of CARVYKTI™ throughout the U.S. in 2022 and beyond, to ensure that we can provide CARVYKTI™ treatment to oncologists and their patients in a reliable and timely manner.

"This approval of Janssen's first cell therapy is a testament to our continuing commitment in oncology to deliver new therapeutic options and drive toward our vision of the elimination of cancer," said Mathai Mammen, M.D., Ph.D., Executive Vice President, Pharmaceuticals, Janssen Research & Development, LLC, Johnson & Johnson. "Today's approval underscores our determination to develop therapies that can help patients living with what remains an intractable blood cancer today and at the same time offer hope for the future."

The longer-term efficacy and safety profile of ciltacabtagene autoleucel is being assessed in the ongoing CARTITUDE-1 study. Two-year follow-up results recently [presented](#) at the American Society of Hematology (ASH) 2021 Annual Meeting showed that 98 percent of patients treated with ciltacabtagene autoleucel for RRMM responded to therapy (98 percent overall response rate [ORR] (n=97), and a majority of patients achieving sustained depth of response with 83 percent of patients achieving an sCR at the 22-month follow-up.<sup>4</sup>

### **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 the B-cell maturation antigen (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>1</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 ciltacabtagene autoleucel.

In April 2021, Janssen [announced](#) the submission of a Marketing Authorisation Application to the European Medicines Agency seeking approval of CARVYKTI™ for the treatment of patients with relapsed and/or refractory multiple myeloma. In addition to a U.S. Breakthrough Therapy Designation [granted](#) in December 2019, ciltacabtagene autoleucel received a Breakthrough Therapy Designation in China in August 2020. Janssen also received an Orphan Drug Designation for CARVYKTI™ from the U.S. FDA in February 2019, and from the European Commission in February 2020.

### **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. All 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, or no longer responds, to an IMiD, a PI and an anti-CD38 monoclonal antibody.<sup>1</sup>

### **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>3</sup> When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. 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>5</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>2</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)<sup>1</sup> 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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

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

†*Sundar Jagannath, M.D. has been a paid consultant 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™. 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> CARVYKTI™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

<sup>2</sup> American Cancer Society. "What Is Multiple Myeloma?" Available at: <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed February 2022.

<sup>3</sup> Gandhi, U., Cornell, R., Lakshman A., et al. Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy. *Leukemia*. 2019;33(9). <http://www.ncbi.nlm.nih.gov/pubmed/30858549>.

<sup>4</sup> Martin, T. Updated Results From CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen-Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma. Abstract #549 [Oral]. Presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition.

<sup>5</sup> American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html>. Accessed February 2022.