**Media Contacts:**
Brian Kenney
+1 215-620-0111

Satu Glawe
+49 172-294-6264

**Investor Relations:**
Jessica Moore
+1 732-524-2955

**U.S. Medical Inquiries:**
+1 800-526-7736

# New Data from CARTITUDE-1 Study Show Continued Deep and Durable Responses of Ciltacabtagene Autoleucel (cilta-cel) in Treatment of Heavily Pretreated Patients with Multiple Myeloma

*Data presented at ASH 2021 show 83 percent of patients achieved a stringent complete response at median follow-up of 22-months*

*92 percent of evaluable patients achieved minimal residual disease negativity, with progression-free survival and overall survival sustained in those patients for ≥6 and ≥12 months*

**ATLANTA, Ga., December 12, 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today longer-term results from the Phase 1b/2 CARTITUDE-1 study evaluating the efficacy and safety of ciltacabtagene autoleucel (cilta-cel), an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy administered as a single infusion, in the treatment of patients with relapsed and/or refractory multiple myeloma. The data, featured as an oral presentation at the American Society of Hematology (ASH) 2021 Annual Meeting (Abstract #549) and selected as part of the

Highlights of ASH program, show that patients receiving cilta-cel continue to demonstrate deep and durable responses, with a very high overall response rate (ORR) of 98 percent.[1]

Responses in the 97 patients treated with cilta-cel deepened over time, with 83 percent of patients achieving a stringent complete response (sCR) at median 22-month follow-up, an increase from 80 percent at the 18-month median follow-up data presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, and from 67 percent at the 12.4-month median follow-up data presented at ASH 2020.[1] At median follow-up of 22-months, median progression-free survival (PFS) and median overall survival (OS) were not reached, suggesting long-term durability of responses and survival for patients. Two-year PFS and OS rates were 61 percent (95 percent Confidence Interval [CI], 48.5–70.4) and 74 percent (95 percent CI, 61.9–82.7), respectively.[1] Among 61 minimal residual disease (MRD) evaluable patients, 92 percent of patients achieved MRD negativity at $10^{-5}$.[1] The two-year PFS rates in patients who achieved MRD negativity for ≥6 and ≥12 months were 91 percent (95 percent CI, 67.1–97.8) and 100 percent, respectively.[1]

"Unfortunately, patients with multiple myeloma for whom at least three treatment regimens have stopped working, face a median survival of less than a year with currently available treatments," said Thomas Martin, M.D.†, Director of Clinical Research, Clinical Professor of Medicine, Adult Leukemia and Bone Marrow Transplantation Program, Associate Director, Myeloma Program and Co-Leader, Hematopoietic Malignancies Program, at UCSF Helen Diller Family Comprehensive Cancer Center, and principal study investigator. "The CARTITUDE-1 data presented at ASH 2021 builds upon previous results that show that a single infusion of cilta-cel resulted in durable responses and long-term survival across the study population, further confirming the potential of cilta-cel in offering patients and physicians a valuable new treatment option."

Median time to first response was one month (range, 0.9-10.7), with responses deepening over time.[1] Additionally, median time to best response was 2.6 months (range, 0.9-17.8) and median time to complete response or better was 2.9 months (range, 0.9-17.8).[1] Twelve percent of patients achieved a very good partial response and 3 percent achieved a partial response.[1] The study included patients who received a median of six prior treatment

regimens (range, 3-18).[1] All patients were triple-class [immunomodulatory agent (IMiD), proteasome inhibitor (PI) and an 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.[1]

"These data add to the growing body of evidence supporting the potential clinical benefit of cilta-cel in the treatment of patients with relapsed and/or refractory multiple myeloma, a population in need of new options," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. "We look forward to further evaluation of cilta-cel as part of our comprehensive CARTITUDE clinical development program that includes studying cilta-cel in patients with newly diagnosed multiple myeloma."

The data demonstrated a consistent safety profile for cilta-cel and no new safety signals were observed with longer follow-up.[1] In 18-month follow-up data presented at ASCO 2021, the most common hematologic adverse events (AEs) observed were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (53 percent).[2] At 18-months, cytokine release syndrome (CRS) of any grade was observed in 95 percent of patients with a median duration of four days (range, 1-97), and 99 percent of which resolved within 14 days of onset.[2] Of the 92 patients with CRS at 18-month follow-up, 95 percent experienced Grade 1/2 events.[2] Neurotoxicity of any grade was observed in 21 percent (n=20) of patients at 18-months, with Grade 3 or higher neurotoxicity observed in 10 percent (n=10) of patients.[1] There were no new events of cilta-cel–related neurotoxicity or movement and neurocognitive treatment (MNT) emergent adverse events reported in CARTITUDE-1 since the median 12.4-month follow-up data were presented at ASH 2020.[1] At the 22-month data cut-off, more than 200 patients have been dosed with cilta-cel across the CARTITUDE clinical development program and MNT incidence has decreased to less than one percent since the implementation of MNT mitigation measures.[1]

**Subgroup Analysis of the Phase 1b/2 CARTITUDE-1 Study**

In the abstract accepted for presentation at ASH 2021, data demonstrated that cilta-cel resulted in deep, durable responses in all evaluated subgroups in CARTITUDE-1 at median

follow-up of 18-months.[3] An ORR range of 95 to 100 percent was observed in patients across all subgroups, including those with high-risk cytogenetics, International Staging System (ISS) stage III multiple myeloma, baseline bone marrow cells ≥60 percent, and presence of baseline plasmacytomas.[3] In patients with ISS stage III, high risk cytogenetics and with baseline plasmacytomas, median duration of response appeared shorter and 18-month PFS and OS rates lower.[3] The cilta-cel safety profile across the subgroups was consistent with the overall population, with no new safety signals.[3] The latest data from this analysis will be presented in a poster presentation (Abstract #3938) at ASH 2021 on Monday, December 13.

**About CARTITUDE-1**

CARTITUDE-1 (NCT03548207) is an ongoing Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed and/or refractory multiple myeloma, 99 percent of whom were refractory to the last line of treatment; 88 percent of whom were triple-class refractory, meaning their cancer did not or no longer responds to an immunomodulatory agent (IMiD), a proteasome inhibitor (PI) and an anti-CD38 antibody.

The primary objective of the Phase 1b portion of the study, involving 29 patients, was to characterize the safety and confirm the dose of cilta-cel, informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2). Based on the safety profile observed in this portion of the study, outpatient dosing is being evaluated in additional CARTITUDE studies. The Phase 2 portion of the study, involving 68 additional patients, is evaluating the efficacy of cilta-cel with overall response as the primary endpoint.

**About Cilta-cel**

Cilta-cel is a BCMA-directed, genetically modified autologous T-cell immunotherapy administered as a single infusion, 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 cilta-cel 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.

In December 2017, Janssen Biotech, Inc. entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialize cilta-cel.

In December 2020, Janssen announced initiation of a rolling submission of its BLA to the U.S. FDA for cilta-cel, which was accepted under Priority Review in May 2021. In November 2021, Janssen announced the extension of the U.S. FDA Prescription Drug User Fee Act (PDUFA) date. The U.S. FDA has conditionally accepted CARVYKTI™ as the brand name for cilta-cel, if approved.

**About Multiple Myeloma**

Multiple myeloma is an incurable blood cancer that affects some white blood cell called plasma cells, which are found in the bone marrow.[4] When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. In 2021, 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.[5] 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.[4]

**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. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*[†]Thomas Martin, 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 product development and the potential benefits and treatment impact of 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 Research & Development, LLC, Janssen Biotech, Inc., 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 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission.*

*Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of 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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[1] 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]. To be presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition Annual Meeting.

[2] Usmani, S. Ciltacabtagene autoleucel, a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy, in relapsed/refractory multiple myeloma (R/R MM): Updated results from CARTITUDE-1. Abstract #8005 [Oral]. Presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

[3] Jakubowiak, A. Efficacy and Safety of Ciltacabtagene Autoleucel in Patients With Relapsed/Refractory Multiple Myeloma: CARTITUDE-1 Subgroup Analysis. Abstract #3938 [Poster]. To be presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition Annual Meeting.

[4] American Cancer Society. "What Is Multiple Myeloma?" Available at: https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html. Accessed December 2021.

[5] 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 December 2021.