**Media Inquiries:**
Brian Kenney
Phone: 1-215-620-0111

**Investor Relations:**
Christopher DelOrefice
Phone: 1-732-524-2955

Lesley Fishman
Phone: 1-732-524-3922

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

# Janssen Announces BCMA CAR-T Therapy JNJ-4528 Granted U.S. FDA Breakthrough Therapy Designation for the Treatment of Relapsed or Refractory Multiple Myeloma

*Newest designation for JNJ-4528 is supported by Phase 1b/2 CARTITUDE-1 study in adults with relapsed or refractory multiple myeloma*

*Initial results from CARTITUDE-1 study to premiere at the American Society of Hematology Annual Meeting*

**RARITAN, NJ, December 6, 2019** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for JNJ-68284528 (JNJ-4528), an investigational B cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy in previously treated patients with multiple myeloma. Breakthrough Therapy Designation is granted to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

"The granting of Breakthrough Therapy Designation for JNJ-4528 is a significant milestone as we continue to accelerate the global development of this innovative CAR-T therapy in

collaboration with Legend Biotech," said Sen Zhuang, M.D., Ph.D., Vice President, Oncology Clinical Development, Janssen Research & Development, LLC. "We look forward to continuing to work closely with the U.S. Food and Drug Administration to advance the clinical development program for JNJ-4528 and ultimately bring this BCMA-targeted immunotherapy to patients living with multiple myeloma who are in need of a new therapeutic option."

The Breakthrough Therapy Designation is supported by data from the Phase 1b/2 CARTITUDE-1 study (NCT03548207), an open-label, multicenter clinical trial evaluating the safety and efficacy of JNJ-4528 in adults with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy or are double refractory to a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD); have received a PI, IMiD and an anti-CD38 antibody; and who progressed on or within 12 months of their last line of therapy.[1] Currently active in the U.S., the primary objective of the Phase 1b portion of the study is to characterize the safety of JNJ-4528 and confirm the dose for future clinical trials. Phase 2 is evaluating efficacy with a primary endpoint of overall response rate, as defined by the International Myeloma Working Group response criteria, as well as duration of response and overall tolerability. Initial data from the CARTITUDE-1 study will be presented for the first time at the American Society of Hematology Annual Meeting (Abstract #577).

The CARTITUDE-1 study design was informed by the Phase 1 LEGEND-2 study (NCT03090659), the first-in-human study with LCAR-B38M CAR-T cells.[2] In February 2019, the FDA granted Janssen an Orphan Drug Designation for JNJ-4528. On April 3, 2019, Janssen announced the European Medicines Agency granted a PRIME (PRIority MEdicines) designation for JNJ-4528 based on the CARTITUDE-1 and LEGEND-2 studies.

JNJ-4528, a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies, identifies the investigational product being studied in the U.S. and Europe.[3] LCAR-B38M, which has the same CAR construct, identifies the investigational product in China. In December 2017, Janssen entered into a worldwide collaboration and license agreement with Legend Biotech to jointly develop and commercialize LCAR-B38M in multiple myeloma. In China, the Phase 2 CARTIFAN-1 confirmatory trial (NCT03758417), sponsored by Nanjing Legend Biotech Co. Ltd. in collaboration with Janssen, is actively recruiting to further evaluate LCAR-B38M in patients with advanced relapsed or refractory multiple myeloma.[4]

**About CAR-T and BCMA**

CAR-T cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient's own immune system. BCMA is a protein that is highly expressed on myeloma cells.

**About CARTITUDE-1**

CARTITUDE-1 (NCT03548207) is an ongoing Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of JNJ-68284528 in adults with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy or are double refractory to a PI and an IMiD; have received a PI, IMiD and an anti-CD38 antibody; and who progressed on or within 12 months of their last line of therapy.[1] The primary objective of the Phase 1b portion of the study is to characterize the safety and confirm the dose of JNJ-68284528, which was informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2). The primary objective for the Phase 2 portion of the study is to evaluate the efficacy of JNJ-68284528 (primary endpoint: overall response rate as defined by the International Myeloma Working Group response criteria).

**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.[5,6] When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow.[5,6] In 2019, it is estimated that more than 32,000 people will be diagnosed, and nearly 13,000 will die from the disease in the United States.[7] While some patients with multiple myeloma have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[8]

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

# # #

*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 JNJ-4528. 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 or 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 December 30, 2018, 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. Neither 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.*

[1] ClinicalTrials.gov. A Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against B-Cell Maturation Antigen (BCMA) in Participants With Relapsed or Refractory Multiple

Myeloma. NCT03548207. Available at: https://clinicaltrials.gov/ct2/show/NCT03548207. Accessed December 2019.
[2] ClinicalTrials.gov. LCAR-B38M-02 cells in treating relapsed/refractory (R/R) multiple myeloma (LEGEND-2). NCT03090659. Available at: https://clinicaltrials.gov/ct2/show/NCT03090659. Accessed December 2019.
[3] Fan F. Poster presented at the 17th International Myeloma Workshop, September 12-15, 2019; Boston, MA. Abstract number FP-181, #413.
[4] ClinicalTrials.gov. A Study of LCAR-B38M CAR-T Cells, a Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against B-cell Maturation Antigen (BCMA) in Chinese Participants With Relapsed or Refractory Multiple Myeloma (CARTIFAN-1). NCT03758417. Available at: https://clinicaltrials.gov/ct2/show/NCT03758417. Accessed December 2019.
[5] Kumar SK, et al. Leukemia. 2012 Jan; 26(1):149-57.
[6] American Cancer Society. "What Is Multiple Myeloma?." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed December 2019.
[7] American Cancer Society. "Key Statistics for Multiple Myeloma." Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed December 2019.
[8] American Cancer Society. "Diagnosing Multiple Myeloma From Test Results." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed December 2019.