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**Janssen Announces Investigational CAR-T Therapy JNJ-68284528 Granted
PRIME Designation by the European Medicines Agency**

*PRIME (PRIority Medicines) designation based on clinical study results evaluating
safety and efficacy of novel CAR-T therapy in the treatment of patients with
advanced relapsed or refractory multiple myeloma*

BEERSE, BELGIUM, 3 April 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the European Medicines Agency (EMA) has granted a PRIME (PRIority Medicines) designation for the company’s investigational B-cell maturation antigen (BCMA) chimeric antigen receptor T-cell (CAR-T) therapy, JNJ-68284528 (JNJ-4528). PRIME offers enhanced interaction and early dialogue to optimise development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.¹

“The PRIME designation of this novel BCMA CAR-T therapy highlights the value of regulatory innovation in the European Union,” said Sjaak Bot, Vice President, Head EMEA Regulatory Affairs at Janssen Biologics B.V. “We hope to bring this important advance to

patients as quickly as possible and this PRIME designation, the first for Janssen, marks an important milestone towards potential market approval.”

The PRIME designation is based on results from the Phase 1/2 LEGEND-2 study ([NCT03090659](#)) evaluating LCAR-B38M CAR-T cells, sponsored by Nanjing Legend Biotech Co.,² and the Phase 1b/2 CARTITUDE-1 study ([NCT03548207](#)) evaluating JNJ-4528, sponsored by Janssen and being conducted in collaboration with Legend Biotech USA Inc.³ Results from the LEGEND-2 study were [presented](#) at the American Society of Hematology (ASH) 2018 annual meeting.⁴ Results from the CARTITUDE-1 study will be presented in the future.

“CAR-T therapy is an exciting therapeutic platform that harnesses the patient’s immune system to attack tumour cells,” said Sen Zhuang, M.D., Ph.D., Vice President, Oncology Clinical Development, Janssen Research & Development, LLC. “We continue to advance this novel BCMA targeted CAR-T therapy through clinical studies globally as we strive to bring it to the patients with multiple myeloma around the world.”

JNJ-4528 is currently being investigated for the treatment of patients with multiple myeloma who have received at least three prior regimens, including a proteasome inhibitor (PI), an immunomodulatory drug (IMiD), and an anti-CD38 antibody, and have documented disease progression within 12 months of starting the most recent therapy, or are double refractory to an IMiD and PI.³ These patients have few available treatment options and are often faced with poor outcomes.⁵

In [December 2017](#), Janssen entered into a worldwide collaboration and licence agreement with Legend Biotech to jointly develop and commercialise LCAR-B38M in multiple myeloma.⁶ In China, the Phase 2 CARTIFAN-1 confirmatory trial ([NCT03758417](#)), sponsored by Nanjing Legend Biotech Co. Ltd. and registered with the Center for Drug Evaluation (CTR20181007), is actively recruiting to further evaluate LCAR-B38M in patients with advanced relapsed or refractory multiple myeloma.⁷

About LEGEND-2

LEGEND-2 ([NCT03090659](#)) is an ongoing single-arm, open-label Phase 1/2 study being conducted at four participating hospitals in China evaluating the efficacy and safety of LCAR-B38M for the treatment of relapsed or refractory multiple myeloma.²

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.⁸ By targeting BCMA via this approach, CAR-T therapies may have the potential to redefine treatment for multiple myeloma.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells.⁹ In Europe, more than 48,200 people were diagnosed with multiple myeloma in 2018, and more than 30,800 patients died.¹⁰ Almost 40 percent of patients with multiple myeloma do not reach five-year survival.¹¹

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.¹² Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.^{13,14} Relapsed myeloma is when the disease has returned after a period of initial, partial or complete remission and does not meet the definition of being refractory.¹⁵ While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.¹⁶ Patients who relapse after treatment with standard therapies, including PIs and IMiDs, have poor prognoses and few treatment options available.¹⁷

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/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Biologics B.V. and Janssen Research & Development, LLC are part 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 LCAR-B38M and JNJ-68284528. 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 materialise, actual results could vary materially from the expectations and projections of Janssen Biologics B.V., Janssen Research & Development, LLC, any of the Janssen Pharmaceutical Companies of Johnson & Johnson 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 behaviour 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company'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, 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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