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Janssen Announces Initiation of Phase 1b/2 Clinical Development Program Evaluating JNJ-68284528 CAR-T Cells for the Treatment of Multiple Myeloma

Planned Start of Clinical Program and Clearance of U.S. Food and Drug Administration Investigational New Drug Application Reflect Progress in Strategic Partnership with Legend Biotech

SPRING HOUSE, Pa., May 30, 2018 /PRNewswire/ -- The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the initiation of a Phase 1b/2 clinical development program studying JNJ-68284528 (developed based on Legend's LCAR-B38M), a chimeric antigen receptor T cell (CAR-T) therapy directed against B cell maturation antigen (BCMA), in patients with relapsed or refractory multiple myeloma. The planned start of the Phase 1b/2 study (68284528MMY2001), scheduled to begin enrollment in the second half of 2018, follows the U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application submitted by Janssen.

As announced in December 2017, Janssen entered into a worldwide collaboration and license agreement with Legend Biotech USA Inc. and Legend Biotech Ireland Limited ("Legend"), subsidiaries of GenScript Biotech Corporation. Under the terms of the agreement, Legend granted Janssen Biotech, Inc. a worldwide license to jointly develop and commercialize JNJ-68284528 in multiple myeloma.

"We are committed to rapidly advancing JNJ-68284528, and we are pleased to initiate a global clinical development program to further evaluate this cell-based therapy," said Peter F. Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "As we strive to eliminate multiple myeloma, we are hopeful that this BCMA targeted CAR-T therapy will play an important role in the treatment of this disease."

The Phase 1b/2, open-label, multicenter study will evaluate the safety and efficacy of JNJ-68284528 in adults with relapsed or refractory multiple myeloma. The primary objective of the Phase 1b portion of the study is to characterize the safety and establish 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 [partial response or better] as defined by the International Myeloma Working Group response criteria).

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. By targeting BCMA via a CAR-T approach, CAR-T therapies may have the potential to redefine the treatment paradigm for multiple myeloma and potentially advance towards cures for patients with the disease.

About Multiple Myeloma
Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[1,2] Refractory cancer occurs when a patient's disease is resistant to treatment or in the case of multiple myeloma, patients progress within 60 days of their last therapy.[3,4] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[5] In 2018, it is estimated that 30,700 people will be diagnosed and 12,770 will die from the disease in the United States.[6] Most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood counts, fatigue, calcium elevation, kidney problems or infections.[7]

About the Janssen Pharmaceutical Companies
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Biotech, Inc. 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 related to a clinical development program studying LCAR-B38M, in patients with relapsed or refractory multiple myeloma. 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: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company and Legend to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and 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, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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. The Janssen Pharmaceutical Companies of Johnson & Johnson and Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

[1] Kumar, SK et al. Leukemia. 2012 Jan; 26(1):149-57.

[2] American Cancer Society. "What Is Multiple Myeloma?." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed March 2018.

[3] National Cancer Institute. "NCI Dictionary of Cancer Terms: Refractory." Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=350245. Accessed March 2018.

[4] Richardson, et al. "The Treatment of Relapsed and Refractory Multiple Myeloma." ASH Education Book. January 1, 2007 vol. 2007 no. 1 317-323.

[5] National Cancer Institute. "NCI Dictionary of Cancer Terms: Relapsed." Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=45866. Accessed March 2018.

[6] American Cancer Society. "Key Statistics for Multiple Myeloma." Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed March 2018.

[7] American Cancer Society. "Diagnosing Multiple Myeloma From Test Results." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed March 2018.

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