News Release

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Janssen Enters Worldwide Collaboration and License Agreement with Cellular Biomedicine Group to Develop Next Generation CAR-T Therapies

Investigational CD20-targeted CAR-Ts Enhance Janssen's B-cell Malignancy Portfolio

Agreement Deepens Janssen's Leadership in Oncology and Hematology, and Accelerates Commitment to Delivering Transformational Cell Therapies

HORSHAM, Pa., May 2, 2023 – Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today that it has entered into a worldwide collaboration and license agreement with Cellular Biomedicine Group Inc. (CBMG) to develop, manufacture and commercialize next-generation chimeric antigen receptor (CAR) T-cell therapies for the treatment of B-cell malignancies. These investigational CD20-directed autologous CAR-Ts have demonstrated promising overall and complete response rates in Phase 1 studies in patients with relapsed/refractory non-Hodgkin's lymphoma (NHL) in China, with the majority of study participants having diffuse large B-cell lymphoma (DLBCL), the most common type of aggressive lymphoma accounting for approximately one-third of B-cell lymphomas globally.[1,2]

DLBCL is characterized by the uncontrolled rapid growth of a type of immune cell called lymphocytes.[3] CD20 and CD19 are antigens commonly found on the surface of the cells.[4] As

many as half of patients with DLBCL eventually become refractory to first-line treatment and require additional treatment options.[5] C-CAR039 is a novel bispecific CAR-T therapy targeting both CD19 and CD20 antigens and has received U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) clearance, and Regenerative Medicine Advanced Therapy and Fast Track designations for the treatment of patients with relapsed or refractory (R/R) DLBCL. A Phase 1b study in the U.S. evaluating C-CAR039 in the treatment of patients with R/R DLBCL is underway. C-CAR066 is an optimized novel CD20 targeted CAR-T therapy that has also received U.S. FDA IND clearance, and a Phase 1b study in patients with R/R DLBCL is anticipated to begin in the second half of 2023.

"We are committed to advancing the science and treatment of B-cell malignancies, especially in DLBCL where deeper responses and long-term remissions represent a persistent unmet need," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. "A tenet to our continued innovation is a focus on accelerating the development of cell therapies as we strive to profoundly transform patient outcomes and, ultimately, progress potentially curative regimens."

Through the collaboration, Janssen enhances its portfolio in B-cell malignancies and strengthens its more than two-decade legacy in hematology, while deepening its commitment to accelerate development, manufacturing and commercialization capabilities to deliver best-in-class cell therapies. Under terms of the agreement, CBMG will grant Janssen a worldwide license to develop and commercialize the CAR-T assets, except in Greater China. Janssen and CBMG will negotiate an option for Janssen to commercialize the products in the China territory. Janssen will make an upfront payment of $245 million that will be accounted for in the second quarter as a research and development expense. Additional future payments will be based upon the achievement of certain development, regulatory and sales milestones, as well as tiered royalty payments on worldwide net trade sales, excluding Greater China.

Johnson & Johnson estimates that this collaboration, licensing agreement and development program will have an annual approximate 10 cent negative impact on earnings per share (EPS) in 2023 and 2024. The charge will largely apply to the second quarter and the company is maintaining its 2023 guidance.

The closing of the transaction is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and is expected to close in the second quarter of 2023.

"Our innovation strategy is agnostic to the source of breakthrough science, platforms, targets and medicines from the global life science ecosystem," said Yusri Elsayed, M.D., M.HSc., Ph.D., Vice President, Disease Area Leader, Hematologic Malignancies, Janssen Research & Development, LLC. "The Cellular Biomedicine Group team has discovered differentiated cell therapies with clinically validated CD20 CAR constructs, and we look forward to harnessing our expertise, capabilities and scale to lead the global development of these innovative CAR-T products."

About B-cell Malignances

B-cell malignancies, or B-cell lymphomas, are a type of cancer that arise from B cells (a type of immune system cell). Most B-cell lymphomas are NHL, and DLBCL is the most common. Globally, it is estimated that more than 540,000 new cases of NHL occurred in 2020, and more than 259,000 people died from the disease.[6,7] DLBCL is most common in the U.S. and Western Europe, and the incidence has increased by more than 50 percent in 20 countries since the late 20th century.[2] Other types of B-cell malignancies include Burkitt lymphoma, mantle cell lymphoma (MCL), and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Prognosis and treatment depend on type and stage of the disease.[6,7]

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenGlobal. Janssen Biotech, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 a new collaboration and product development. 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, 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 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, 2023, 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, 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.

[1] American Cancer Society. What Is Non-Hodgkin Lymphoma? Available at: https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html. Accessed February 2023.
[2] Rare Disease Advisor. Diffuse Large B-Cell Lymphoma (DLBCL). Available at: https://www.rarediseaseadvisor.com/disease-info-pages/diffuse-large-b-cell-lymphoma-epidemiology/. Accessed February 2023.
[3] Diffuse Large B-Cell Lymphoma. Available at: https://www.ncbi.nlm.nih.gov/books/NBK557796/. Accessed April 2023.
[4] CD19-Targeted Immunotherapies for Diffuse Large B-Cell Lymphoma. Available at: https://www.frontiersin.org/articles/10.3389/fimmu.2022.837457/full. Accessed April 2023.
[5] Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5649550/. Accessed April 2023.
[6] National Cancer Institute. B-cell lymphoma. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/b-cell-lymphoma. Accessed February 2023.
[7] Global Cancer Observatory. Cancer Today: Non-Hodgkin Lymphoma. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/34-Non-hodgkin-lymphoma-fact-sheet.pdf. Accessed February 2023.