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NEWS RELEASE

Johnson & Johnson's dual-targeting CAR T-cell therapy shows encouraging first results in large B-cell lymphoma

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Phase 1b study suggests a promising safety profile and highlights the potential of a novel dual-targeting CD19/CD20 CAR T in patients with relapsed or refractory disease

75-80% complete response rate among evaluable patients at the recommended Phase 2 dose

MILAN, June 13, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today the first clinical data from an ongoing Phase 1b study for JNJ-90014496 (JNJ-4496), an investigational dual-targeting anti-CD19/CD20 bispecific autologous chimeric antigen receptor (CAR) T-cell therapy, being studied in patients with relapsed or refractory large B-cell lymphoma (R/R LBCL) who have not been previously treated with CAR T-cell therapy.[1] Findings demonstrate the potential of JNJ-4496 in the treatment of patients with R/R LBCL, including R/R diffuse large B-cell lymphoma (DLBCL) – the most common type of aggressive lymphoma, a blood cancer that originates in the lymphatic system.[1,2] These data were presented as an oral presentation at the **2025 European Hematology Association (EHA) Congress** (**Abstract #S239**).[1]

JNJ-4496, formerly known as C-CAR039, is a dual-targeting CAR T designed to bind to both CD19 and CD20 antigens — two cell surface proteins commonly expressed on malignant B-cells. This design, including a 4-1BB costimulatory domain, is intended to enhance binding strength and persistence, also potentially addressing common mechanisms of resistance in relapsed or refractory disease.

In the Phase 1b dose confirmation study (**NCT05421663**) in patients with R/R LBCL, data at the recommended Phase 2 dose (RP2D) were reported in patients with a median follow-up of 4 months. Results informed a RP2D of JNJ-4496

at 75 million CAR+ T-cells. Among the 22 patients in the RP2D group where efficacy was assessed, those who received one prior line of therapy (n=10) had an objective response rate (ORR) of 100 percent and a complete response rate (CRR) of 80 percent (95 percent confidence interval (CI), 69, 100). In the patients who had received two or more prior lines of therapy (n=12), the ORR was 92 percent and the CRR was 75 percent (95 percent CI, 62, 100).[1]

"There is a pressing need to continue advancing therapies for patients with relapsed or refractory diffuse large B-cell lymphoma. Only about 40 percent of patients have long-term remissions with currently available single-antigen-targeting CD19 CAR T therapies," said Krish Patel*, M.D., Director of Lymphoma Research, Sarah Cannon Research Institute (SCRI), and principal study investigator. "The data presented today show encouraging clinical activity and promising safety, and represent a step forward in delivering a potential new treatment option to patients living with the most common type of aggressive lymphoma."

Within the RP2D safety group (n=25), 52 percent of patients (n=13) received two or more prior lines of therapy, and 56 percent (n=14) received bridging therapy. In the RP2D cohort studied, no cases of Grade 3 or 4 cytokine release syndrome were observed. Two patients had immune effector cell-associated neurotoxicity syndrome (ICANS), one Grade 1 and one Grade 3. The Grade 3 event occurred in a patient with central nervous system (CNS) lymphoma. Overall, 84 percent of patients (n=21) had Grade 3/4 treatment-emergent adverse events (TEAEs), and 28 percent (n=7) reported serious TEAEs. The most common Grade 3/4 TEAE was neutropenia, a reduction in white blood cells (72 percent). One patient experienced a Grade 3 infection.[1]

"We're really excited to share the first results for our dual-targeting anti-CD19/CD20 CAR T-cell therapy in relapsed or refractory large B-cell lymphoma, underscoring our more than decade-long commitment to addressing unmet needs for patients with B-cell malignancies," said Jeffrey Infante, M.D., Vice President of Early Clinical Development and Translational Research at Johnson & Johnson Innovative Medicine. "As we continue to unlock the full potential of CAR T-cell therapies through novel next-generation approaches, these promising data reinforce earlier long-term findings and highlight the potential of JNJ-4496 to improve outcomes for patients."

These data are advancing our pipeline of CAR T therapies for the treatment of B-cell malignancies and are an extension of our worldwide collaboration and licensing agreement initiated with AbelZeta Inc. (formerly Cellular Biomedicine Group, Inc.) in 2023 to develop and commercialize next-generation CAR T-cell therapies (excluding Greater China). A Phase 1 study for C-CAR039 was conducted in China for the treatment of patients with B-cell non-Hodgkin lymphoma (predominantly LBCL).[3] Johnson & Johnson is also evaluating the safety and efficacy of this asset (known as JNJ-4496 outside of Greater China) through a separate study involving a global patient population.[4] In addition to the oral presentation of JNJ-4496 at EHA, the global clinical study data will be presented at the 2025 International Conference on Malignant Lymphoma from June 17—21.

About large B-cell lymphoma

Large B-cell lymphoma is a type of non-Hodgkin lymphoma (NHL), a blood cancer that originates in the lymphatic system, arising from abnormal B cells, a type of white blood cell responsible for producing antibodies to fight infections.[2] The malignant cells grow rapidly in lymph nodes or other organs and can spread quickly throughout the body.[2] These abnormal cells are larger than normal, healthy B-cells.[2] Diffuse (D) LBCL is the most common and aggressive type where cells are spread out (diffuse) rather than grouped together when they are examined under a microscope.[2] DLBCL accounts for approximately 40 percent of all NHL cases globally and is estimated to have 150,000 new cases diagnosed each year.[5] While some patients respond to initial treatment, up to 40 percent can relapse or become refractory to therapy.[6] LBCL and DLBCL patients often face limited treatment options and a poor prognosis, highlighting the urgent need for innovative therapies. Common symptoms include rapidly growing lymph nodes, fever, night sweats, weight loss, and fatigue.[2]

About 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 product development and the potential benefits and treatment impact of JNJ-90014496. 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 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 most recent Annual Report on Form 10-K, 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnotes:

[*] Dr. Krish Patel, Director of Lymphoma Research, Sarah Cannon Research Institute (SCRI), U.S., has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

[1] Patel K et al. A Global Phase 1b Study Of JNJ-90014496, A CD19/CD20 Bi-Specific Chimeric Antigen Receptor (CAR) T-Cell Therapy, In Patients (Pts) With Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL). 2025 European Hematology Association. **https://library.ehaweb.org/eha/2025/eha2025-congress/4159316/matthew.ku.a.global.phase.1b.study.of.jnj-90014496.a.cd19.cd20.bi-specific.html**. Last accessed June 2025.

[2] Lymphoma Action. Diffuse Large B-Cell Lymphoma. **https://lymphoma-action.org.uk/types-lymphoma-non-hodgkin-lymphoma/diffuse-large-b-cell-lymphoma**. Last accessed June 2025.

[3] ClinicalTrials.gov. Study of C-CAR039 in relapsed/refractory B-cell non-Hodgkin lymphoma. Identifier NCT05149391. **https://clinicaltrials.gov/study/NCT05149391?term=C-CAR039&rank=1**. Accessed June 2025.

[4] **Clinicaltrials.gov**. A Phase 1b Multicenter, Open-Label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CART-Cell Therapy in Adult Participants With B-Cell Non-Hodgkin Lymphoma. Identifier NCT05421663. **https://clinicaltrials.gov/study/NCT05421663**. Last accessed June 2025.

[5] Berhan A et al. Diffuse large B cell lymphoma (DLBCL): epidemiology, pathophysiology, risk stratification, advancement in diagnostic approaches and prospects: narrative review. Discov Oncol. 2025 Feb 15;16:184. **https://link.springer.com/content/pdf/10.1007/s12672-025-01958-w.pdf.** Last accessed June 2025.

[6] García-Sancho AM et al. Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma: New Approved Options. J Clin Med. 2023 Dec 22;13(1):70. **https://www.mdpi.com/2077-0383/13/1/70.** Last accessed June 2025.

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