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NEWS RELEASE

Early results from Johnson & Johnson's trispecific antibody show promising response in heavily pretreated multiple myeloma patients

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Phase 1 trial demonstrates encouraging clinical activity of investigational immunotherapy for relapsed or refractory multiple myeloma

Novel investigational dual-antigen-targeting immunotherapy binds to B-cell maturation antigen (BCMA) and GPRC5D on myeloma cells, as well as CD3 on T-cells

CHICAGO, June 3, 2025 /PRNewswire/ -- Johnson & Johnson announced today initial Phase 1 results of JNJ-79635322 (JNJ-5322), a novel investigational trispecific antibody (TsAb) in patients with relapsed or refractory multiple myeloma. Among the 36 patients who received the recommended phase 2 dose (RP2D), the overall response rate (ORR) was 86.1 percent. In the 27 patients who were naive to BCMA and GPRC5D directed therapies, the ORR was 100 percent at the RP2D. Findings were featured in an oral presentation at the **2025 American Society of Clinical Oncology (ASCO) Annual Meeting** (Abstract #**7505**). The study will also be featured as one of the six best abstracts during the Plenary Abstracts Session at the **2025 European Hematology Association (EHA) Congress** (Abstract #**S100**).[1]

JNJ-5322 has a novel and distinct structure that builds upon the experience with two approved first-in-class bispecific antibodies: teclistamab and talquetamab. Unlike these bispecific antibodies, JNJ-5322 is a single molecule that simultaneously binds to three distinct targets (BCMA and GPRC5D on multiple myeloma cells, as well as CD3 on T-cells). JNJ-5322 targets two myeloma antigens, with the goal of overcoming tumor heterogeneity and preventing the development of resistance.

In the Phase 1, first-in-human study (**NCT05652335**), researchers investigated escalating doses of JNJ-5322 in heavily pretreated patients with relapsed or refractory multiple myeloma. In the trial, 126 patients received JNJ-5322 with a median follow-up of 8.2 months. The recommended RP2D of 100 mg Q4W consists of one step-up dose of 5 mg and monthly dosing with 100 mg thereafter.

"The response rate with JNJ-5322 is encouraging as we explore the potential of this trispecific antibody for the treatment of relapsed or refractory multiple myeloma patients," said Niels van de Donk, M.D., Ph. D., VU University Medical Center, Amsterdam, Netherlands. "In addition to its monthly dosing and promising efficacy, the results indicate a promising safety profile and that further study of JNJ-5322 is warranted."

"These promising data are a major step forward as Johnson & Johnson works to transform outcomes in oncology with next-generation immunotherapies, building on our leading portfolio of complementary and combinable therapies. We look forward to seeing the results of planned Phase 2 and Phase 3 studies," said Jordan Schecter, M.D., Vice President, Research & Development, Multiple Myeloma, Johnson & Johnson Innovative Medicine. "We hope to redefine what's possible in terms of efficacy and safety, creating another strong treatment option clinicians can choose based on the needs of their patients with relapsed or refractory multiple myeloma."

The most common adverse event was cytokine release syndrome (CRS), occurring in 59 percent of patients, but no events were Grade 3 or higher. Twenty-eight percent of patients experienced Grade 3 or higher infections. Five patients had dose-limiting toxicities, and four treatment emergent patient deaths due to adverse events were reported, with one death caused by adenoviral encephalitis related to the drug.

Taste-related AEs were reported in 58 percent of patients, majority Grade 1. The incidence of other GPRC5D-related oral AEs was low, with dry mouth reported in 17 percent of patients (no Grade 2 at RP2D) and dysphagia reported in less than 4 percent of patients (no reported events at the RP2D). In addition, grade 1/2 weight loss occurred in 6% (RP2D) and 12% (all doses) of patients, with no Grade ≥3 weight loss events.

About Multiple Myeloma

Multiple myeloma is a blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[2] In multiple myeloma, these malignant plasma cells proliferate and replace normal cells in the bone marrow.[3] Multiple myeloma is the second most common blood cancer worldwide and remains an incurable disease.[4] In 2024, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 will die from the disease.[5] People with multiple myeloma have a 5-year survival rate of 59.8 percent. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[6,7]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at **https://www.jnj.com/** or at **www.innovativemedicine.jnj.com**. Follow us at **@JNJInnovMed**. Janssen Research & Development, LLC and Janssen Biotech, Inc., and Janssen Global Services, LLC are Johnson & Johnson companies.

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-79635322. 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 **http://www.sec.gov**, **http://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.

[*] Niels van de Donk, M.D., Ph. D., VU University Medical Center, Amsterdam, Netherlands, has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

[1] NWCJ van de Donk, et. al. First-in-human study of JNJ-79635322 (JNJ-5322), a novel, next-generation trispecific antibody (TsAb), in patients (pts) with relapsed/refractory multiple myeloma (RRMM): Initial phase 1 results. ASCO 2025. June 3, 2025.

[2] Rajkumar SV. Multiple Myeloma: 2020 Update on Diagnosis, Risk-Stratification and Management. Am J Hematol. 2020;95(5):548-5672020;95(5):548-567. **http://www.ncbi.nlm.nih.gov/pubmed/32212178**

[3] National Cancer Institute. Plasma Cell Neoplasms. Accessed August 2024. Available at: **https://www.cancer.gov/types/myeloma/patient/myeloma-treatment-pdq**

[4] Multiple Myeloma. City of Hope, 2022. Multiple Myeloma: Causes, Symptoms & Treatments. Accessed August 2024. Available at: **https://www.cancercenter.com/cancer-types/multiple-myeloma**

[5] American Cancer Society. Myeloma Cancer Statistics. Accessed August 2024. Available at: **https://cancerstatisticscenter.cancer.org/types/myeloma**

[6] American Cancer Society. What is Multiple Myeloma? Accessed August 2024. Available at: **https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html**

[7] American Cancer Society. Multiple Myeloma Early Detection, Diagnosis, and Staging. Accessed August 2024. Available at: **https://www.cancer.org/cancer/types/multiple-myeloma/detection-diagnosis-staging/detection.html**

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