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NEWS RELEASE

Johnson & Johnson reports 73% PSA response rate with investigational pasritamig-based immunotherapy combination in advanced prostate cancer

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- First-of-its-kind dual-antigen-targeted bispecific regimen of pasritamig and JNJ-9401 directed at two prostate cancer proteins, KLK2 and PSMA, using complementary signals to activate T cells against cancer
- Deep and sustained PSA responses observed with every-six-week dosing, with 73% (11 of 15 patients) achieving reductions of at least 50% and nearly half achieving reductions of at least 90% in Phase 1 study
- With an encouraging safety profile, findings show potential for outpatient dosing as the combination advances to Phase 3

NEW BRUNSWICK, N.J., Nov. 8, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced promising first-in-human Phase 1 results for the investigational combination of pasritamig and JNJ-9401, two bispecific antibodies designed to work together to drive the body's immune response against advanced prostate cancer. At the recommended regimen, 73 percent (11 of 15 patients) achieved reductions of at least 50 percent in prostate-specific antigen (PSA), a marker used to monitor prostate cancer activity, including 47 percent (7 of 15 patients) who achieved reductions of at least 90 percent. Results were presented in a late-breaking oral session at the **Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting** (Abstract #1175).[1]

The combination represents the first dual-tumor-antigen-targeted bispecific antibody regimen clinically evaluated in prostate cancer, targeting kallikrein-related peptidase 2 (KLK2) and prostate-specific membrane antigen (PSMA) through complementary T-cell signals designed to activate and enhance the function of immune cells against

cancer. In the study, deep and sustained PSA responses were observed, with all seven patients who achieved reductions of at least 90 percent remaining on treatment for more than six months without disease progression. No Grade 3 or higher treatment-related adverse events were reported in this early analysis.[1]

A first-of-its-kind approach: targeting two prostate cancer proteins with complementary T-cell signals

For patients with metastatic castration-resistant prostate cancer (mCRPC), treatment remains challenging as the disease progresses and available options become more limited.[2] Median overall survival is approximately two to three years, highlighting the need for continued innovation.[3,4] While immunotherapies have transformed the treatment of some cancers, their role in prostate cancer has historically been limited, and immune checkpoint inhibitors have shown minimal clinical benefit.[5]

Bispecific antibodies are designed to help the immune system recognize and attack cancer by activating T cells, a process that can be enhanced by generating two complementary signals.[6,7] Pasritamig, a first-in-class, bispecific antibody targeting KLK2 has demonstrated single-agent antitumor activity,[8] and is designed to provide the first signal by directing T cells toward prostate cancer cells. JNJ-9401, a novel bispecific antibody targeting PSMA, provides a second signal designed to strengthen and sustain T cell activity.

Expert and company perspectives on the potential of this dual-antigen targeted bispecific regimen

"Prostate cancer has long been difficult to treat with immunotherapy, which makes the activity we're seeing particularly interesting," said Laura Graham, M.D.,* Assistant Professor of Medicine-Medical Oncology at the University of Colorado School of Medicine. "By combining two complementary approaches to T-cell activation, we are exploring a new way to engage the immune system against this disease. The depth of PSA reductions observed in this study, including responses sustained for six months or longer, provides encouraging early evidence for the pasritamig-JNJ-9401 combination that warrants further investigation in a larger Phase 3 study."

"This novel dual-antigen-targeted bispecific regimen combines pasritamig, a foundational component of our prostate cancer pipeline, with JNJ-9401, highlighting the potential of complementary mechanisms working together," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson. "With this combination now in Phase 3 development, we are building on the early promise of this approach as we work to bring new treatment options to patients with advanced disease."

Early results show promising deep and sustained PSA reductions

The ongoing, open-label, multicenter Phase 1 study is evaluating the safety and preliminary clinical activity of pasritamig in combination with JNJ-9401 in patients with metastatic castration-resistant prostate cancer (mCRPC), also known as metastatic androgen pathway modulation-resistant prostate cancer (mAPMR).[1]

These preliminary findings are based on a small number of patients at the recommended regimen, and further evaluation is needed to determine the clinical benefit and safety of the combination in a larger population.[1]

As of June 15, 2026, 144 patients had enrolled in the study. Patients treated at the recommended regimen were heavily pretreated, having received a median of four prior lines of systemic therapy (range, two to six). Among the 15 patients treated at this regimen, 73 percent achieved PSA reductions of at least 50 percent and 47 percent achieved reductions of at least 90 percent. Four patients achieved undetectable PSA levels. All seven patients who achieved PSA reductions of at least 90 percent remained on treatment for more than six months without disease progression.[1]

At the recommended regimen, no Grade 3 or higher treatment-related adverse events, dose-limiting toxicities, or treatment-related adverse events leading to discontinuation or death were reported. Cytokine release syndrome (CRS), an inflammatory reaction that can occur when T cells are activated, was observed in three patients (20 percent). All cases were mild (Grade 1), presenting as temporary fever, and none required treatment with tocilizumab. No cases of immune effector cell-associated neurotoxicity syndrome (ICANS) were reported.[1]

The recommended regimen consists of JNJ-9401 200 mg administered subcutaneously every six weeks in combination with pasritamig 300 mg administered intravenously every six weeks, following two initial weekly pasritamig step-up doses. The findings suggest the combination has potential to be administered on this schedule in an outpatient setting.[1]

Advancing a new generation of immunotherapy combinations into Phase 3

The combination is being evaluated in the ongoing Phase 3 KLK2-comPAS (**NCT07164443**) study, which is investigating whether adding JNJ-9401 to pasritamig can improve outcomes for patients with mCRPC.[9] The study represents an important next step in Johnson & Johnson's broader development program for pasritamig, which is being evaluated both as a single agent and in combination with other therapies across advanced prostate cancer.

About the study

The Phase 1 study (**NCT06095089**) is an open-label, multicenter trial evaluating the safety and clinical activity of pasritamig in combination with JNJ-9401 in patients with metastatic castration-resistant prostate cancer (mCRPC) who have received at least one prior systemic therapy. In Part 1, JNJ-9401 was dose escalated in combination with

fixed-dose pasritamig, with primary objectives of evaluating safety and determining the recommended regimen. Dose expansion was initiated at the recommended regimen, including a frontline mCRPC cohort. The recommended regimen is JNJ-9401 200 mg administered subcutaneously every six weeks in combination with pasritamig 300 mg administered intravenously every six weeks, following two weekly pasritamig step-up doses. Treatment is administered in an outpatient setting.[10]

About pasritamig and JNJ-9401

Pasritamig and JNJ-9401 are investigational bispecific antibodies designed to work together to activate and enhance the immune response against prostate cancer. Pasritamig, a first-in-class KLK2xCD3 bispecific antibody, is designed to direct T cells to prostate cancer cells, while JNJ-9401, a PSMAxCD28 costimulatory bispecific antibody, is designed to provide an additional signal that enhances T-cell activation and function. By targeting two different prostate cancer proteins, KLK2 and PSMA, the combination is designed to deliver complementary signals to T cells.

Pasritamig is being studied as a monotherapy and in combination with other therapies across advanced prostate cancer. Pasritamig with or without JNJ-9401 is being evaluated in the Phase 3 KLK2-comPAS study in metastatic castration-resistant prostate cancer and pasritamig plus docetaxel is being evaluated in the Phase 3 KLK2-PASenger study in first-line mCRPC.

About metastatic castration-resistant prostate cancer (mCRPC)

Metastatic castration-resistant prostate cancer (mCRPC), also known as metastatic androgen pathway modulation-resistant prostate cancer (mAPMR), is an advanced form of prostate cancer that continues to progress despite treatments that target the androgen receptor pathway.[2] As the disease progresses, it can spread to other parts of the body, including the bones and lymph nodes, and patients may receive additional treatments such as chemotherapy and radioligand therapy targeting prostate-specific membrane antigen (PSMA).[11]

Patients with metastatic prostate cancer that has become resistant to androgen pathway modulation face poor outcomes, with survival varying based on factors including the location and extent of disease, prior treatment history and response to therapy. Median overall survival ranges from approximately 13.5 to 31.6 months depending on the site of metastasis.[3,4]

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**.

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 pasritamig and JNJ-9401. 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**, **www.investor.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.

*Laura Graham, M.D., has provided consulting, advisory and speaking services to Johnson & Johnson. She has not been paid for any media work.

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