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Johnson & Johnson unveils first-in-human results for pasritamig, showing early anti-tumor activity in prostate cancer

Pasritamig, a first-in-class bispecific T-cell-engaging antibody, shows potential in mCRPC with outpatient dosing designed for the community setting

Data show low rates of treatment-related adverse events, signaling human kallikrein 2 (KLK2) as a novel, highly specific target

CHICAGO, JUNE 1, 2025 – Johnson & Johnson announced today new data from a Phase 1 study evaluating pasritamig (JNJ-78278343), a first-in-class bispecific antibody that activates T-cells to harness the body's immune system against prostate cancer cells, showing promise in patients with advanced disease who have progressed after multiple lines of therapy. These first data on pasritamig, from the first-in-human study, demonstrate that pasritamig appears well-tolerated and exhibits a promising antitumor activity in patients with metastatic castration-resistant prostate cancer (mCRPC), highlighting the potential of KLK2 as a novel target for T-cell engagement in advanced disease.[1] These data were presented as an oral presentation (Abstract #5017) at the 2025 American Society of Clinical Oncology Annual Meeting and published simultaneously in *The Journal of Clinical Oncology*.

Pasritamig is a novel T-cell engager designed to bind both CD3 on T-cells and KLK2—a prostate-specific antigen with minimal expression outside of the prostate. Pasritamig activates T-cells by binding to CD3 and directing them to KLK2-expressing tumor cells, engaging the body's immune system to specifically target these cancerous cells. This differentiated approach aims to deliver a targeted treatment for patients with advanced prostate cancer, while potentially reducing the high-grade toxicities historically associated with T-cell engagers.

"These first-in-human results for pasritamig are highly encouraging, demonstrating that KLK2 is a viable target for T-cell engagers in metastatic castration-resistant prostate cancer," said Capucine Baldini*, M.D., Ph.D., Drug Development Department (DITEP), Institut Gustave Roussy, and presenting author. "The data show a promising safety profile, with manageable adverse events and no AEs leading to treatment discontinuations or ICANS observed, with 40 percent of patients having no treatment-related AEs at all. Given the limited treatment options for mCRPC, these findings support further investigation of pasritamig and the role of KLK2-targeted T-cell therapies as a potential new approach for patients with aggressive disease."

"Metastatic castration-resistant prostate cancer remains one of the most difficult stages of prostate cancer to treat, particularly for patients who haven't responded well to previous treatments," said Jeff Infante, M.D., Vice President of Early Clinical Development and Translational Research at Johnson & Johnson Innovative Medicine. "This investigational approach underscores our commitment to developing innovative and practice-changing medicines that are well-tolerated and can be easily administered in community practice settings."

The Phase 1 first-in-human study (NCT04898634) evaluated 174 patients with ages ranging from 36 to 89 years old and on average having received four prior therapies (range 1-13). The recommended phase 2 dose (RP2D) of pasritamig was 3.5mg on day 1, 18mg on day 8, 300mg intravenously on day 15 and then once every six weeks. The RP2D safety group also included patients treated once every three weeks as the toxicity profiles were very similar. The RP2D efficacy group only included patients treated at the RP2D once every six weeks.[1]

Within the RP2D safety group (n=45), treated once every three or six weeks, 100 percent had previously received androgen receptor pathway inhibitors, 75.6 percent had undergone taxane chemotherapy, and 37.8 percent had been treated with Lutetium 177 vipivotide tetraxetan prostate-specific membrane antigen radioligand therapy.[1] The most common treatment-related adverse events (TRAEs) were Grade 1/2 infusion-related reactions (24.4 percent), Grade 1 cytokine release syndrome (CRS) presenting as fever only (8.9 percent, no steroid or tocilizumab was administered) and no reports of higher grade CRS. No TRAEs leading to treatment discontinuation or dose reduction were reported and no immune effector cell-associated neurotoxicity syndrome (ICANS) was observed. Grade 3 TRAEs were infrequent with 4.4 percent of patients reporting transient AST/ALT increases and neutropenia. There were no dose-limiting toxicities reported. The favorable safety

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profile of the RP2D regimen enabled convenient outpatient administration on a patient-friendly, once-every-six-weeks schedule.[1]

Of the patients in the RP2D efficacy group (n=33), treated once every six weeks, 42.4 percent achieved a 50 percent or greater reduction in their prostate-specific antigen (PSA) levels with a median rPFS of 7.9 months (95 percent confidence interval [CI] 2.9, not estimable [NE]) and 21.2 percent of patients continuing therapy. Treatment with pasritamig showed durable disease control and rPFS that compares favorably to historical data in heavily pretreated patients with mCRPC.[1]

Metastatic castration-resistant prostate cancer occurs in a significant portion of prostate cancer patients, with many progressing despite initial therapies.[2] Overall survival from diagnosis of mCRPC patients ranges from 13.5 to 31.6 months, and lower in patients who have progressed on therapy.[3] Treatment options remain limited, underscoring the urgent need for safer and more effective therapies.[4]

About Pasritamig (JNJ-78278343)
Pasritamig (JNJ-78278343) is an investigational T-cell-engaging bispecific antibody (bsAb) targeting human kallikrein 2 (KLK2) on prostate cancer cells and CD3 on T-cells. This approach is being evaluated in heavily pretreated patients with metastatic castration-resistant prostate cancer (mCRPC), a patient population with limited treatment options.

About Metastatic Castration-Resistant Prostate Cancer (mCRPC)
Metastatic castration-resistant prostate cancer (mCRPC) is a challenging and aggressive stage of prostate cancer where the disease progresses despite androgen deprivation therapy.[2] Patients often experience metastasis to bones and lymph nodes, leading to poor outcomes and limited treatment options, including chemotherapy and second-line hormone therapies.[5] The median overall survival ranges from 13.5 to 31.6 months depending on the site of metastasis, with a typical range of 15–36 months across the broader population.[3,6] Survival rates can vary significantly depending on factors such as prior treatment history, disease burden, and response to therapy. The need for more effective treatments is critical, as the disease continues to impact a large number of men globally, with mCRPC being responsible for a substantial number of prostate cancer-related deaths.

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, Janssen Biotech, Inc., Janssen Global Services, LLC and Janssen Scientific Affairs, 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-78278343. 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.

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Source: Johnson & Johnson

**Dr. Capucine Baldini has provided consulting, advisory, and speaking services to Johnson & Johnson; Dr. Baldini has not been paid for any media work.*

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[1] Baldini, C., et al. Phase 1 Study Results of Pasritamig (JNJ-78278343) in Metastatic Castration-Resistant Prostate Cancer. 2025 American Society of Clinical Oncology Annual Meeting. June 2025.

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