

## Early study results from Johnson & Johnson show promising antitumor activity with combination of pasritamig and docetaxel in advanced prostate cancer

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Combination demonstrates deep PSA responses and favorable safety profile with plans to advance into Phase 3

Data highlight the potential of this first-in-class next-generation T-cell engager to expand the role of immunotherapy in prostate cancer

RARITAN, N.J., Feb. 26, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) today announced preliminary results from a Phase 1b study evaluating pasritamig (JNJ-78278343), a first-in-class bispecific T-cell engaging antibody, in combination with docetaxel in patients with metastatic castration-resistant prostate cancer. The combination demonstrated a safety profile consistent with docetaxel alone, with no new or unexpected safety signals observed. The regimen also showed clinically meaningful efficacy, including high rates of prostate-specific antigen (PSA) responses and sustained PSA reductions, supporting continued development and advancement into Phase 3 studies. The results were presented for the first time at the 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium (Abstract #171).<sup>1</sup>

Pasritamig is designed to engage the immune system through a novel mechanism of action, binding CD3 on T cells and human kallikrein 2 (KLK2). KLK2 is a novel, highly specific prostate cancer target with minimal expression outside prostate tissue. By both activating and directing T cells to KLK2-expressing tumor cells, pasritamig enables targeted immune engagement. This differentiated, prostate-specific approach was intentionally built to focus immune activity on prostate cancer cells, which may help limit effects on healthy tissue, and supports administration in a doctor's office rather than hospital setting.

"These data represent an important step forward for patients with advanced prostate cancer," said Professor Shahneen Sandhu,\* M.D., Ph.D., MBBS, FRACP, Associate Professor, Consultant Medical Oncologist and researcher at Peter MacCallum Cancer Centre, and study investigator. "In a disease where outcomes remain poor for many patients, seeing encouraging clinical activity alongside a favorable safety profile in combination with docetaxel reinforces the potential of this approach and supports further clinical development."

"Based on these findings, we are increasingly confident in the potential of pasritamig to meaningfully improve outcomes for people with prostate cancer," said Charles Drake, M.D., Ph.D., Vice President, Prostate Cancer and Cross Cancer Immuno-Oncology, Johnson & Johnson. "The ability to combine pasritamig with docetaxel, where prior approaches in the field have fallen short, gives us a strong foundation for Phase 3 development. What we're seeing with this combination, including deep and durable PSA responses, underscores the promise of this combination immunotherapy approach and our commitment to advancing innovation that can make a difference for patients."

## Detailed Study Results

In the study, pasritamig was evaluated in combination with docetaxel in an outpatient setting in patients with metastatic castration-resistant prostate cancer whose disease had progressed following androgen receptor pathway inhibitor therapy. Approximately half of the patients (45 percent) had received at least one prior taxane-based regimen. The primary endpoint was safety and identification of the recommended regimen for further development in Phase 2/3 studies, with secondary and exploratory endpoints assessing clinical activity, including PSA response rates.<sup>1</sup>

As of December 9, 2025, 51 patients had received pasritamig plus docetaxel, including patients who were pretreated with a median of three prior therapies (range, 1-9). Reductions of 50 percent or greater in PSA levels were achieved in 64.7 percent of patients overall and in 75.0 percent of taxane-naïve patients. Reductions of 90 percent or greater in PSA levels were achieved in 39.2 percent of patients overall and 53.6 percent of taxane-naïve patients. Among taxane-naïve patients with bone-only disease, confirmed PSA reductions of 50 percent or greater and 90 percent or greater were observed in 88.2 percent and 76.5 percent of patients, respectively. Patients were able to continue pasritamig beyond docetaxel discontinuation. Those patients received a median of six docetaxel doses every three weeks and eight pasritamig doses every six weeks, supporting the potential for sustained disease control over time.<sup>1</sup>

The safety profile of pasritamig plus docetaxel was consistent with the known safety profile of docetaxel in metastatic castration-resistant prostate cancer. The most common treatment-related adverse events (TRAEs) occurring in at least 20 percent of patients included fatigue (60.8 percent), alopecia (41.2 percent), diarrhea and nausea (31.4 percent each), peripheral edema (27.5 percent), peripheral sensory neuropathy (25.5 percent) and

dysgeusia (23.5 percent). Pasritamig-related adverse events occurring in at least 10 percent of patients were fatigue (33.3 percent) and non-chronic diarrhea (11.8 percent). Grade 3 or higher TRAEs attributed to docetaxel were observed in 29.4 percent of patients, compared with only two percent attributed to pasritamig. No patients experienced cytokine release syndrome of any grade or treatment-related deaths.<sup>1</sup>

Two ongoing Phase 3 studies are evaluating pasritamig in the metastatic castration-resistant prostate cancer setting. KLK2-compPAS (**NCT07164443**) is evaluating pasritamig as monotherapy, and KLK2-PASenger (**NCT07225946**) is evaluating pasritamig in combination with docetaxel.<sup>2,3</sup> Beyond these Phase 3 studies, pasritamig is also being evaluated in earlier-phase combination studies. Pasritamig monotherapy has received Breakthrough Therapy Designation in China and Fast Track designation from the U.S. Food and Drug Administration, supporting its continued clinical development.

## About the Study

The Phase 1b study (**NCT05818683**) is an open-label trial evaluating the safety and clinical activity of pasritamig in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed following treatment with an androgen receptor pathway inhibitor. The primary objective is to determine the recommended regimen for further development based on safety, with secondary and exploratory endpoints assessing clinical activity. Pasritamig was administered intravenously every six weeks, with initial step-up doses given during the first treatment cycle, in combination with docetaxel administered intravenously every three weeks. Treatment was delivered in an outpatient setting. Corticosteroids were used only as standard premedication for docetaxel, and hematopoietic growth factor support was permitted as needed.<sup>4</sup>

## About Pasritamig (JNJ-78278343)

Pasritamig (JNJ-78278343) is an investigational T-cell-redirecting bispecific antibody (bsAb) targeting human kallikrein 2 (KLK2) on prostate cancer cells and CD3 receptor complexes on T cells, leveraging the body's immune system to selectively target and eliminate cancer cells. This innovative approach is being evaluated in 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.<sup>5</sup> Patients often experience metastasis to bones and lymph nodes, leading to poor outcomes and limited treatment options, including chemotherapy and second-line hormone therapies.<sup>6</sup> The median overall survival ranges from 13.5 to 31.6 months depending on the

site of metastasis, with a typical range of 15 to 36 months across the broader population.<sup>7,8</sup> 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 metastatic castration-resistant prostate cancer (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](http://www.innovativemedicine.jnj.com). Follow us at [@JNJInnovMed](https://twitter.com/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 (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](http://www.sec.gov), [www.jnj.com](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.

\*Professor Shahneen Sandhu, M.D., Ph.D., MBBS, FRACP has provided consulting, advisory, and speaking services

to Johnson & Johnson; she has not been paid for any media work.

Source: Johnson & Johnson

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<sup>1</sup> Patel MR, et al. Safety and Efficacy of Pasritamig (PAS) + Docetaxel (DOCE) in Participants with Metastatic Castration-Resistant Prostate Cancer (mCRPC): Initial Results of a Phase 1b Study. Presented at: 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium; February 26, 2026; San Francisco, California.

<sup>2</sup> **ClinicalTrials.gov**. A Study of Pasritamig Versus Placebo in Late Line Metastatic Castration-resistant Prostate Cancer (mCRPC) (KLK2-comPAS). <https://clinicaltrials.gov/study/NCT07164443>. Accessed February 2026.

<sup>3</sup> **ClinicalTrials.gov**. A Study of Pasritamig With Docetaxel Versus Docetaxel in Participants With Metastatic Castration-Resistant Prostate Cancer (KLK2-PASenger). <https://clinicaltrials.gov/study/NCT07225946>. Accessed February 2026.

<sup>4</sup> **ClinicalTrials.gov**. A Study of JNJ-78278343 in Combination With Either JNJ-63723283 (Cetrelimab), Taxane Chemotherapy, or Androgen Receptor Pathway Inhibitors for Metastatic Prostate Cancer. <https://www.clinicaltrials.gov/study/NCT05818683>. Accessed February 2026.

<sup>5</sup> Kushwaha PP, Gupta S. New insights for drug resistance in metastatic castration-resistant prostate cancer. *Cancer Drug Resist.* 2022;5(3):846-849. Published 2022 Aug 2. doi:10.20517/cdr.2022.83

<sup>6</sup> Wallace K, Landsteiner A, Bunner S, Engel-Nitz N, Luckenbaugh A. Epidemiology and mortality of metastatic castration-resistant prostate cancer (mCRPC) in a managed care population in the United States. *J Clin Oncol.* 2020;38(15 suppl):e13592. doi:10.1200/JCO.2020.38.15\_suppl.e13592

<sup>7</sup> Wallace KL, Landsteiner A, Bunner SH, Engel-Nitz NM, Luckenbaugh AN. Increasing prevalence of metastatic castration-resistant prostate cancer in a managed care population in the United States. *Cancer Causes Control.* 2021;32(12):1365-1374. doi:10.1007/s10552-021-01484-4

<sup>8</sup> Kawahara T, Saigusa Y, Yoneyama S, et al. Development and validation of a survival nomogram and calculator for male patients with metastatic castration-resistant prostate cancer treated with abiraterone acetate and/or enzalutamide. *BMC Cancer.* 2023;23:214. doi:10.1186/s12885-023-10700-0

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