Novartis International AG
CH-4002 Basel
Switzerland

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PRESS RELEASE

New real-world data reinforce earlier use of Pluvicto™ before chemotherapy in metastatic castration-resistant prostate cancer

- *In the real-world, Pluvicto™ showed 13.5 months median PFS in chemo-naïve patients with PSMA-positive mCRPC*
- *Real-world evidence showed Pluvicto achieved longer PFS when initiated after one ARPI instead of multiple ARPIs*
- *A separate analysis of treatment patterns in metastatic hormone-sensitive prostate cancer suggest significant opportunity for increased guideline adherence*

Basel, February 24, 2026 – Novartis today announced multiple US real-world studies delivering new insights across metastatic prostate cancer care. The analyses utilize data from Novartis' PRECISION platform to evaluate Pluvicto™ (lutetium (^{177}Lu) vipivotide tetraxetan) effectiveness and sequencing as well as real-world treatment patterns in earlier metastatic disease. These studies will be presented at the ASCO Genitourinary Cancers Symposium on February 26, 2026.

Pluvicto shows real-world effectiveness in taxane-naïve mCRPC patients
Real-world use of Pluvicto resulted in a median progression-free survival (PFS) of 13.5 months (95% CI: 11.7 – 14.7 months) in men with metastatic castration-resistant prostate cancer (mCRPC) who had been treated with ≥1 androgen receptor pathway inhibitor (ARPI) and were taxane-naïve. Results showed chemo-naïve patients treated with Pluvicto after only 1 ARPI had longer median PFS (15.8 months; 95% CI: 11.7 - 18.6 months) than those who received Pluvicto after multiple ARPIs (12.7 months; 95% CI: 10.7 - 14.0 months)[1].

"This analysis validates what many of us have seen in the clinic – that lutetium Lu 177 vipivotide tetraxetan can achieve clinically relevant responses across a diverse set of patients and in various practice settings," said Daniel George, Professor of Medicine and Surgery at Duke University School of Medicine. "These results show reassuring consistency with the PSMAfore pivotal trial and should strengthen clinicians' confidence in using radioligand therapy for patients after one ARPI."

Outcome	All patients (n=500)	1 ARPI (n=256)	>1 ARPI (n=244)
Median PFS	13.5 months (95% CI: 11.7 - 14.7 months)	15.8 months (95% CI: 11.7 - 18.6 months)	12.7 months (95% CI: 10.7 - 14.0 months)
PSA50	62.6%	61.4%	63.8%

PSA50 indicates ≥50% decline in prostate-specific antigen levels from baseline

The real-world findings are consistent with PSMAfore, which supported the approval of Pluvicto for patients with PSMA-positive mCRPC who have been treated with an ARPI and are considered appropriate to delay taxane-based chemotherapy. In PSMAfore, Pluvicto more than doubled median rPFS compared to a change in ARPI (11.6 months vs. 5.6 months) at an updated exploratory analysis[2]. These findings should be considered within the context of varying study designs, patient populations, and endpoints across the analyzed cohorts*.

“Pluvicto is redefining the standard of care for metastatic prostate cancer. Novartis is committed to advancing the science of radioligand therapy through ongoing rigorous clinical development and real-world evidence generation,” said Liviu Niculescu, Chief Medical Officer, US at Novartis. “These real-world findings build on the evidence from our robust clinical trial program and contribute to a broader understanding of treatment outcomes observed in routine practice.”

Study assesses response with systemic therapies when used after Pluvicto
A second study showed that patients with mCRPC achieved meaningful clinical responses with systemic therapies after discontinuing Pluvicto (including taxane, ARPI, PARP inhibitor or other), most of whom had prior exposure to ARPI and chemotherapy[2].

Subsequent therapy	**Median PFS**
All (n=442)	8.6 months (95% CI: 7.2 - 10.1 months)
ARPI (n=176)	10.7 months (95% CI: 8.1 - 19.3 months)
Taxane (n=188)	7.2 months (95% CI: 5.9 - 9.4 months)

“With the emergence of new advanced therapies for metastatic prostate cancer, including radioligand therapies, optimizing the sequencing of systemic therapies has become increasingly important for clinicians,” said Dr. Xiao Wei at the Dana-Farber Cancer Institute. “These findings are reassuring, as they suggest that treatment with lutetium Lu 177 vipivotide tetraxetan does not preclude the effectiveness of subsequent therapies for appropriate patients.”

Analysis shows gaps in guideline-adherent care for mHSPC
Despite clear clinical guidelines recommending treatment intensification with androgen deprivation therapy (ADT) and ARPI for metastatic hormone-sensitive prostate cancer (mHSPC), a substantial proportion of men continue to receive ADT alone. In a large US real-world study, nearly four in ten (39.2%) men received ADT monotherapy while just over half (55.5%) received combination ADT+ARPI (n=43,415 patients treated between 2020 and 2025)[5]. While adoption of guideline-recommended therapy is improving, these data underscore a significant remaining opportunity for patients to receive optimal care.

About the PRECISION data platform
PRECISION – the PRostatE Cancer dISease observatION platform – is a US real-world evidence platform developed by Novartis and urology and oncology experts. The platform harmonizes data from more than 56,500 patients with metastatic prostate cancer to generate RWE studies that inform clinical decisions and everyday care.

*Analysis of PFS in the PRECISION data platform included biochemical, radiographic and clinical assessments. In PSMAfore, the primary endpoint was rPFS defined as the time from randomization to radiographic disease progression (assessed by blinded independent central review) or death.

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Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people’s lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

References

1. George DJ, et al. Real-world outcomes of [177Lu]Lu-PSMA-617 in taxane-naïve patients with metastatic castration-resistant prostate cancer (mCRPC): a PRECISION data platform analysis. Presented at ASCO Genitourinary Cancers Symposium, February 26, 2026.
2. Wei XX, et al. Real-world effectiveness of systemic therapies after [177Lu]Lu-PSMA-617 treatment in patients with metastatic castration-resistant prostate cancer (mCRPC): a PRostatE Cancer dISease observatION (PRECISION) data platform analysis. Presented at ASCO Genitourinary Cancers Symposium, February 26–28, 2026.
3. National Comprehensive Cancer Network® (NCCN®) Guidelines. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) - Prostate Cancer. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
4. George DJ, et al. Treatment utilization among patients with metastatic hormone-sensitive prostate cancer (mHSPC) in real-world US settings: a PRostatE Cancer dISease observatION (PRECISION) data platform analysis. Presented at ASCO Genitourinary Cancers Symposium, February 26–28, 2026.
5. Sartor O, et al. Clinical outcomes among patients with metastatic hormone-sensitive prostate cancer (mHSPC) in contemporary real-world US clinical practice: a PRostatE Cancer dISease observatION (PRECISION) data platform analysis. Presented at ASCO Genitourinary Cancers Symposium, February 26–28, 2026.

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Novartis Media Relations
E-mail: media.relations@novartis.com

Novartis Investor Relations
Central investor relations link: +41 61 324 7944
E-mail: investor.relations@novartis.com