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PRESS RELEASE

Pluvicto™ demonstrated consistent efficacy across key patient subgroups in metastatic hormone-sensitive prostate cancer

- *Improved radiographic progression-free survival (rPFS) regardless of disease volume or metastatic presentation achieved with Pluvicto plus standard of care (ARPI + ADT) in PSMAddition*
- *Consistent secondary endpoint results, including PSA progression and time to mCRPC, and safety profile reinforce broad clinical applicability*
- *Promising Phase 1 data for Novartis actinium-based RLT also presented, supporting two Phase 3 trials and reinforcing Novartis global RLT leadership*

Basel, May 31, 2026 – Novartis today announced results showing consistent radiographic progression-free survival (rPFS) improvement across key subgroups with Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) plus standard of care (SoC; androgen receptor pathway inhibitor [ARPI] + androgen deprivation therapy [ADT]) compared to SoC alone in PSMA-positive metastatic hormone-sensitive prostate cancer (mHSPC). These PSMAddition data were presented as an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

The subgroup analysis evaluated outcomes by disease volume (high or low) and disease presentation (*de novo* or recurrent mHSPC). Pluvicto demonstrated a similar rPFS improvement across key subgroups, consistent with the previously reported primary endpoint showing a 28% reduction in the risk of radiographic progression or death (HR 0.72; 95% CI: 0.58, 0.90). Secondary endpoints for disease progression were also consistent. Together, these data support use of Pluvicto as early as PSMA+ metastatic prostate cancer diagnosis.

Subgroup	rPFS hazard ratio for Pluvicto arm vs. control arm
Overall (n=1,144)	0.72 (0.58 – 0.90)
High volume disease (n=779)	0.72 (0.56 – 0.92)
Low volume disease (n=365)	0.73 (0.42 – 1.27)
De novo (n=572)	0.74 (0.54 – 1.01)
Recurrent (n=523)	0.74 (0.53 – 1.04)

Disease volume per CHAARTED criteria; data from second interim analysis for rPFS, DCO 13 Jan 2025

“Metastatic hormone-sensitive prostate cancer is a heterogeneous disease, with disease burden and presentation often dictating how aggressively a patient’s cancer will progress,” said Fred Saad, Professor and Chairman, Department of Surgery, University of Montreal. “The consistent findings demonstrated with Pluvicto across key subgroups, regardless of initial presentation or disease volume, reinforce its potential as a cornerstone of early treatment for a broad range of patients.”

The safety profile was generally consistent across subgroups within each treatment arm, with similar incidence of adverse events (AEs). In PSMAddition, Grade ≥3 AEs were reported in 50.7% of patients in the Pluvicto plus SoC arm, compared to 43% on SoC alone. The most common all-grade AEs were dry mouth, fatigue, nausea, hot flush and anemia.

More than 186,000 men are diagnosed annually with mHSPC, now also known as metastatic androgen pathway modulation-naïve/sensitive prostate cancer (mAPMN/S), globally[*1]. Most patients progress to castration-resistant, or modulation-resistant (mAPMR) disease within 20 months[2,3]. The PSMA biomarker is present in more than 80% of patients with prostate cancer[4-8].

Novartis has filed regulatory submissions in the US, China and Japan based on results from PSMAddition, with first decisions expected in H2 2026.

Promising Phase 1 data from AcTION for actinium-based RLT ^{225}Ac-PSMA-617
Novartis also presented data for its actinium-based RLT, ^{225}Ac-PSMA-617, from the Phase 1 AcTION trial. The data showed promising early antitumor activity with PSA declines and radiographic responses, as well as a manageable safety profile which supports further clinical development in patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC).

“Novartis helped redefine treatment for metastatic prostate cancer with Pluvicto, and we are continuing to push the bar even higher,” said Mark Rutstein, Global Head of Oncology Development at Novartis. “Our actinium program represents the next frontier in radioligand therapy, and with two Phase 3 trials underway, we are working to extend the promise of RLTs to more patients.”

^{225}Ac-PSMA-617 is an investigational actinium-based RLT that targets PSMA with a proven ligand to deliver short-ranged, high-energy alpha-particle radiation directly to prostate cancer cells. ^{225}Ac-PSMA-617 is designed to induce potent tumor cytotoxicity while minimizing exposure to surrounding healthy tissues, reflecting Novartis’ strategy to advance differentiated RLTs across multiple disease stages.

Novartis is enrolling two Phase 3 trials for ^{225}Ac-PSMA-617:
- PSMAcTION evaluating ^{225}Ac-PSMA-617 in mCRPC after Pluvicto, chemotherapy and ARPI
- AcTFirst evaluating ^{225}Ac-PSMA-617 in frontline mCRPC

Radioligand Therapy (RLT) at Novartis
Novartis is reimagining cancer care with RLT for patients with advanced cancers. By harnessing the power of targeted radiation, RLT is designed to deliver treatment directly to target cells anywhere in the body.

As a global leader in this space, Novartis has built integrated capabilities across research, manufacturing, logistics, and patient and provider support to help ensure approved RLTs reach patients reliably and efficiently. Novartis is investigating a broad portfolio of isotopes, ligands, and combination therapies to expand the use of RLT beyond prostate and neuroendocrine tumors.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” or similar expressions, or by express or implied discussions regarding: potential new products; potential new indications for existing products; potential product launches or potential future revenues from any such products; results of ongoing clinical trials; or potential future, pending or announced transactions; potential future sales or earnings; strategy, plans, expectations or intentions, including discussions regarding our continued investment into new R&D capabilities and manufacturing; or our capital structure. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations could be affected by, among other things, uncertainties concerning: global healthcare cost containment, including ongoing government,

payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the success of our key products, commercial priorities and strategy; research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; the development or adoption of new technologies, including artificial intelligence, and new business models; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis
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**.

**Global incidence includes the United States, China, Japan, France, Germany, Italy, Spain and the United Kingdom*

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