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PRESS RELEASE

New PSMAddition data show 58% lower risk of PSA progression with Pluvicto® in metastatic hormone-sensitive prostate cancer

- *More durable, deeper PSA response in patients treated with Pluvicto plus standard of care (ARPI + ADT) vs. SoC alone*
- *Deep PSA reduction higher in patients receiving Pluvicto combination vs. SoC at 12, 24 and 48 weeks*
- *sNDA filed in US, China and Japan; decisions expected H2 2026*

Basel, May 17, 2026 – Novartis today announced new data from PSMAddition demonstrating improved prostate-specific antigen (PSA) responses with Pluvicto® (lutetium (177Lu) vipivotide tetraxetan) combined with standard of care (SoC) in PSMA-positive metastatic hormone sensitive prostate cancer (mHSPC). Data were presented as a rapid oral presentation at the American Urological Association Annual Meeting 2026.

Results show that patients treated with Pluvicto experienced a higher frequency and depth of PSA response when combined with SoC (androgen receptor pathway inhibitor [ARPI] + androgen deprivation therapy [ADT]) compared to SoC alone. Risk of PSA progression was 58% lower (HR 0.42; 95% CI: 0.30-0.59) in patients treated with Pluvicto plus SoC compared to SoC alone.

“Our goal in hormone-sensitive prostate cancer is to attack and delay the cancer before it develops resistance,” said Fred Saad, Professor and Chairman, Department of Surgery, University of Montreal. “The deep and durable PSA response observed by combining 177Lu-PSMA-617 with today’s standard of care, together with earlier reported rPFS data, suggest that treatment intensification with radioligand therapy may help patients delay disease progression."

Nearly all patients (>98%) in both arms had substantial declines in PSA levels. However, more patients treated with Pluvicto plus SoC achieved a deep PSA reduction than those treated with SoC alone, as measured by PSA nadir of <0.2 ng/mL.

Time from randomization	**Patients with PSA <0.2 ng/mL**	
	Pluvicto + ARPI + ADT	*ARPI + ADT*
Week 12	47.6% (235/494)	37.7% (169/448)
Week 24	73.7% (334/453)	59.7% (250/419)
Week 48	87.4% (320/366)	74.9% (295/394)

These results were observed at the second interim analysis for PSMAddition. The safety profile and tolerability of Pluvicto were consistent with its established profile in PSMAfore and VISION. Grade ≥3 adverse events (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.

“These data show that combining Pluvicto with today’s standard of care resulted in deeper PSA responses than ADT plus ARPI alone,” said Mark Rutstein, M.D., Global Head, Oncology Development, Novartis. “As the field moves toward more precision-based approaches and earlier treatment intensification in mHSPC, we are encouraged by the potential for Pluvicto to redefine the standard of care across metastatic prostate cancer.”

Novartis has filed regulatory submissions in the United States, China and Japan, with first decisions expected in H2 2026.

PSA progression signals disease resistance
PSA progression can be an early indicator of emerging disease resistance, and approximately one-third of patients do not achieve undetectable PSA levels with SOC alone[3]. Progression to mCRPC, which typically happens within 20 months of diagnosis, is associated with significantly worse outcomes and a life expectancy less than two years[4-7]. Approximately 186,000 men are diagnosed with mHSPC each year across the US, China, Japan, France, Germany, Italy, Spain and the United Kingdom[1].

About Pluvicto® (lutetium (^{177}Lu) vipivotide tetraxetan)
Pluvicto is an intravenous RLT that combines a targeting compound (a ligand) with a therapeutic radionuclide (a radioactive particle, in this case lutetium-177). After administration into the bloodstream, Pluvicto binds to PSMA-expressing target cells, including prostate cancer cells that express PSMA, a transmembrane protein. Once bound, energy emissions from the radioisotope damage the target cells and nearby cells, disrupting their ability to replicate and/or triggering cell death.

Pluvicto is the only PSMA-targeted agent approved for PSMA+ mCRPC and is the first RLT to demonstrate a clinical benefit for patients with PSMA+ mHSPC in a Phase III trial. Novartis is investigating Pluvicto in oligometastatic prostate cancer, an earlier stage of disease, in the PSMA-DC trial (NCT05939414).

Educational Resources for RLT
To support the integration and safe administration of Novartis RLT products across urology and oncology, Novartis created the RLT Institute. The Institute provides educational resources on theranostics, safety and licensing, facilities and equipment, and clinical workflows to support urologists, oncologists and multidisciplinary teams as they prepare for and integrate RLT into patient care.

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**.

References

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