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PRESS RELEASE

FDA approves Pluvicto for PSMA+ metastatic hormone-sensitive prostate cancer (mHSPC), advancing potential new standard of care across metastatic disease

- *Pluvicto now approved across PSMA+ metastatic prostate cancer, nearly doubling eligible patient population*
- *PSMAddition updated results show Pluvicto reduced risk of progression or death by 33% in combination with standard of care (ADT + ARPI) vs. SoC alone, with positive overall survival trend (HR=0.80)*
- *mHSPC is incurable and about half of men progress within 20 months, highlighting need for differentiated, precision approaches earlier in disease journey*
- *With five US RLT manufacturing sites operational or under construction, Novartis has scale and infrastructure to meet growing demand*

Basel, July 31, 2026 – Novartis today announced the US Food and Drug Administration (FDA) approved Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) in combination with an androgen receptor pathway inhibitor (ARPI) for patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naive/sensitive (mAPMN/S) prostate cancer, commonly known as metastatic hormone-sensitive prostate cancer (mHSPC).

Approval is based on the Phase III PSMAddition trial, which showed Pluvicto reduced the risk of progression or death by 28% (HR 0.72; 95% CI: 0.58–0.90) when combined with standard of care (SoC; ARPI + androgen deprivation therapy [ADT]) compared to SoC alone. At a subsequent updated analysis, the Pluvicto combination further reduced the risk of progression or death by 33% (HR 0.67; 95% CI: 0.55–0.82) with a positive overall survival (OS) trend favoring Pluvicto plus SoC (HR=0.80; 95% CI: 0.63–1.01), as data continue to mature ahead of final OS analysis.

“The treatment landscape for mHSPC is evolving, and this approval reflects a growing recognition that earlier treatment intensification matters,” said Michael Morris, MD, Prostate Cancer Section Head, GU Oncology, Memorial Sloan Kettering Cancer Center, and a Principal Investigator of the study in the US. “Having a radioligand therapy available at this stage meaningfully expands the options for physicians and represents real progress for patients.”

Pluvicto can now be used across all stages of PSMA-positive metastatic prostate cancer, nearly doubling the eligible patient population. The approval builds on its established use in metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer, also known as metastatic castration-resistant prostate cancer (mCRPC).

More than 186,000 men are diagnosed each year with mHSPC globally*[1]. Despite significant treatment advancements, about a third of patients do not achieve undetectable PSA with ARPI-ADT doublet therapy alone

and half will progress to castration-resistant disease within 20 months, highlighting the need for earlier treatment intensification in this disease state[2-6]. The PSMA biomarker is present in more than 80% of patients with prostate cancer[7-11].

"This approval signals a new era in the treatment of prostate cancer, representing a shift toward more targeted, early intervention," said Gina Carithers, CEO and President of the Prostate Cancer Foundation. "This milestone redefines prostate cancer care, ensuring that from day one of their metastatic diagnosis, men have a precision option."

The safety profile and tolerability of Pluvicto were consistent with its established profile in PSMAfore and VISION. At primary analysis, grade ≥3 adverse events (AEs) were reported in 50.7% of patients who received Pluvicto plus SoC compared to 43.0% receiving SoC alone. The most common all-grade AEs were dry mouth, fatigue, nausea, hot flush and anemia. Health-related quality of life was maintained based on longitudinal assessment reflecting patient experience over time, with similar outcomes across arms in PSMAddition.

"Pluvicto is now approved across PSMA-positive metastatic prostate cancer, nearly doubling the number of patients who may benefit from this targeted approach," said Victor Bultó, President, US, Novartis. "Patients with metastatic prostate cancer continue to face significant unmet need, underscoring the importance of introducing precision options earlier in the treatment journey. Backed by nearly a decade of leadership in radioligand therapy and continued investment in science and infrastructure, we are expanding this field and bringing its promise to more patients."

Novartis RLT Patient and Office Support
With five manufacturing sites now operational or under construction in the US, Novartis has established an industry-leading footprint to support its goal of establishing RLT as a fundamental pillar of oncology care. Backed by an integrated end-to-end RLT ecosystem, Novartis can deliver Pluvicto to US treatment sites within 5 days to ensure prompt treatment initiation.

Novartis Patient Support is available to help eligible patients get started on treatment, including help understanding insurance coverage and identifying potential financial assistance options. Patients or providers can speak to a live agent at 1-844-638-7222 or visit https://us.pluvicto.com/support/novartis-patient-support.

About Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)
Pluvicto is an intravenous radioligand therapy (RLT) combining 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 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 across metastatic prostate cancer. Novartis is also investigating Pluvicto in oligometastatic prostate cancer (PSMA-DC, NCT05939414).

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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