

## MEDIA UPDATE

### **Positive survival data for Novartis investigational radioligand therapy <sup>177</sup>Lu-PSMA-617 published in *The New England Journal of Medicine***

- *VISION manuscript shows that <sup>177</sup>Lu-PSMA-617 plus standard of care (SOC) significantly improved overall survival and radiographic progression-free survival for patients with metastatic castration-resistant prostate cancer (mCRPC) compared to SOC alone<sup>1</sup>*
- *US Food and Drug Administration (FDA) granted Breakthrough Therapy designation to <sup>177</sup>Lu-PSMA-617; regulatory submissions to US and EU Health Authorities on track for 2H21*
- *Novartis is a global leader in radioligand therapy, uniquely positioned with broad commercial experience, established manufacturing and supply chain capabilities, and extensive development expertise.*

**Basel, June 23, 2021** — VISION data published today in *The New England Journal of Medicine* (NEJM) shows that <sup>177</sup>Lu-PSMA-617 plus standard of care (SOC) significantly improved both overall survival (HR = 0.62 [95% CI: 0.52–0.74]; P<0.001; median 15.3 vs 11.3 months) and imaging-based progression-free survival (HR = 0.40 [99.2% CI: 0.29–0.57]; P<0.001; median, 8.7 vs 3.4 months) versus SOC alone in patients with progressive PSMA-positive mCRPC<sup>1</sup>. VISION data were first presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6 (see [media release](#)).

“We are proud of these data showing that <sup>177</sup>Lu-PSMA-617 can significantly shrink tumors and extend life for patients with prostate cancer, who have been heavily pre-treated and currently have limited treatment options,” said Jeff Legos, Global Head of Oncology Development, Novartis. “We believe that radioligand therapy with <sup>177</sup>Lu-PSMA-617 has great potential to improve outcomes in advanced prostate cancer and have already started two new Phase III studies in earlier lines of treatment.”

Other data highlighted in the publication and ASCO presentation:

- Median time to first symptomatic skeletal event or death was 11.5 months in the <sup>177</sup>Lu-PSMA-617 plus SOC arm versus 6.8 months in the SOC only arm (P<0.001;  $\alpha=0.05$ ; HR = 0.50 [95% CI: 0.40, 0.62])<sup>1</sup>
- Overall response rate in patients with measurable or non-measurable disease at baseline was 29.8% partial or complete response in the <sup>177</sup>Lu-PSMA-617 plus SOC arm compared to 1.7% partial response in the SOC only arm (two-sided p-value: <0.001)<sup>1</sup>

- The incidence of grade  $\geq 3$  treatment-emergent adverse effects was 52.7% in the  $^{177}\text{Lu}$ -PSMA-617 plus SOC arm vs 38.0% in the SOC only arm<sup>1</sup>
- Serious drug-related treatment emergent adverse events occurred in 9.3% of patients in the  $^{177}\text{Lu}$ -PSMA-617 plus SOC arm compared to 2.4% in the SOC only arm<sup>2</sup>

Two additional studies with  $^{177}\text{Lu}$ -PSMA-617 radioligand therapy in earlier lines of treatment for metastatic prostate cancer are ongoing, investigating potential clinical utility in the mCRPC pre-taxane setting ([PSMAfore](#)) and in the metastatic hormone-sensitive setting ([PSMAddition](#)). Novartis is also evaluating opportunities to investigate  $^{177}\text{Lu}$ -PSMA-617 radioligand therapy in earlier stages of prostate cancer.

The NEJM publication is available online at [www.NEJM.org](http://www.NEJM.org)

#### **About $^{177}\text{Lu}$ -PSMA-617**

$^{177}\text{Lu}$ -PSMA-617 is an investigational PSMA-targeted radioligand therapy for metastatic castration-resistant prostate cancer. It is a type of precision cancer treatment combining a targeting compound (ligand) with a therapeutic radioisotope (a radioactive particle)<sup>3-5</sup>. After administration into the bloodstream,  $^{177}\text{Lu}$ -PSMA-617 binds to prostate cancer cells that express PSMA<sup>6</sup>, a transmembrane protein, with high tumor-to-normal tissue uptake<sup>3,7,8</sup>. Once bound, emissions from the radioisotope damage tumor cells, disrupting their ability to replicate and/or triggering cell death<sup>9-11</sup>. The radiation from the radioisotope works over very short distances to limit damage to surrounding cells<sup>1,3,7</sup>.

#### **About VISION**

VISION is an international, prospective, randomized, open-label, multicenter, phase III study to assess the efficacy and safety of  $^{177}\text{Lu}$ -PSMA-617 (7.4 GBq administered by intravenous infusion every 6 weeks for a maximum of 6 cycles) plus investigator-chosen standard of care in the investigational arm, versus standard of care in the control arm<sup>1</sup>. Patients with PSMA PET-scan positive mCRPC, and progression after prior taxane and androgen receptor pathway inhibitors, were randomized in a 2:1 ratio in favor of the investigational arm<sup>1</sup>. The alternate primary endpoints were rPFS and OS<sup>1</sup>. The study enrolled 831 patients<sup>1</sup>.

#### **Disclaimer**

This investor update 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,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the

effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with 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 contained in this press release as a result of new information, future events or otherwise.

### **About Novartis**

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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