

## **Novartis receives FDA Breakthrough Therapy designation for investigational <sup>177</sup>Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer (mCRPC) " >**

Jun 16, 2021

Novartis announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation (BTD) to <sup>177</sup>Lu-PSMA-617, an investigational radioligand therapy for the treatment of metastatic castration-resistant prostate cancer (mCRPC). Breakthrough Therapy designation is granted to medicines being evaluated for serious conditions where early clinical evidence indicates the potential for substantial improvement over available therapy<sup>1</sup>.

- Breakthrough therapy designation granted based on positive data from the pivotal, Phase III VISION study evaluating <sup>177</sup>Lu-PSMA-617, a targeted radioligand therapy, plus standard of care (SOC), compared to SOC alone, in patients with progressive PSMA-positive mCRPC<sup>2</sup>
- Phase III VISION study demonstrated that <sup>177</sup>Lu-PSMA-617 significantly improved overall survival and radiographic progression-free survival for men with progressive PSMA-positive mCRPC<sup>2</sup>
- The five-year survival rate for patients with metastatic prostate cancer is approximately 30%<sup>3</sup>
- Novartis is a global leader in radioligand therapy, uniquely positioned with broad commercial experience, established manufacturing and supply chain capabilities, and extensive development expertise

Two additional studies with <sup>177</sup>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).

1. U.S. Food and Drug Administration (FDA). Frequently Asked Questions: Breakthrough Therapies. Available from: <https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/frequently-asked-questions-breakthrough-therapies>
2. Morris M, et al. Phase 3 study of <sup>177</sup>Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer (VISION). Oral presentation at: ASCO Annual Meeting; June 6, 2021.
3. SEER. Cancer stat facts: prostate cancer April 2021. [<https://seer.cancer.gov/statfacts/html/prost.html>]

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### 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.

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