

## PULSE UPDATE

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

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).

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### **References**

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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