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PULSE UPDATE

FDA grants Priority Review for investigational targeted radioligand therapy ^{177}Lu-PSMA-617 for patients with metastatic castration-resistant prostate cancer (mCRPC)

Novartis announced today that the US Food and Drug Administration (FDA) has accepted and granted Priority Review to the company's New Drug Application (NDA) for ^{177}Lu-PSMA-617, an investigational targeted radioligand therapy for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in the post androgen receptor pathway inhibition, post taxane-based chemotherapy setting. With Priority Review, the Prescription Drug User Fee Act (PDUFA) date is anticipated in the first half of 2022. Priority Review is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions, as determined by the FDA[1].

- Priority Review is based on positive data from the pivotal, Phase III VISION study showing ^{177}Lu-PSMA-617 plus standard of care (SOC), significantly improved overall survival and radiographic progression-free survival for men with progressive PSMA-positive mCRPC compared to SOC alone[2]
- Two additional studies with ^{177}Lu-PSMA-617 in earlier lines of treatment for metastatic prostate cancer are ongoing, investigating clinical utility in the pre-taxane setting (PSMAfore) and in the metastatic hormone-sensitive setting (PSMAddition)[3,4]

The FDA previously granted Breakthrough Therapy designation for ^{177}Lu-PSMA-617 for the treatment of mCRPC. Data from the VISION study were published in *The New England Journal of Medicine* (NEJM)[2]. Novartis is also evaluating additional opportunities to investigate ^{177}Lu-PSMA-617 in earlier stages of prostate cancer.

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References

1. U.S. Food and Drug Administration (FDA). Priority Review. Available from: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.
2. Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. New England Journal of Medicine 2021. doi: 10.1056/NEJMoa2107322
3. Novartis Pharmaceuticals. ^{177}Lu-PSMA-617 vs. Androgen Receptor-directed Therapy in the Treatment of Progressive Metastatic Castrate Resistant Prostate Cancer (PSMAfore). U.S. National Library of Medicine: Clinical Trials. 2020; NCT04689828
4. Novartis Pharmaceuticals. An International Prospective Open-label, Randomized, Phase III Study Comparing ^{177}Lu-PSMA-617 in Combination With Soc, Versus SoC Alone, in Adult Male Patients With mHSPC (PSMAddition). U.S. National Library of Medicine: Clinical Trials. 2021; NCT04720157

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