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

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Novartis announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation (BTD) to ^{177}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[1].

- Breakthrough therapy designation granted based on positive data from the pivotal, Phase III VISION study evaluating ^{177}Lu-PSMA-617, a targeted radioligand therapy, plus standard of care (SOC), compared to SOC alone, in patients with progressive PSMA-positive mCRPC[2]
- Phase III VISION study demonstrated that ^{177}Lu-PSMA-617 significantly improved overall survival and radiographic progression-free survival for men with progressive PSMA-positive mCRPC[2]
- The five-year survival rate for patients with metastatic prostate cancer is approximately 30%[3]
- 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 ^{177}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).
