Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) – Expanded indication

- On March 28, 2025, Novartis announced the FDA approval of Pluvicto (lutetium Lu 177 vipivotide tetraxetan), for the **treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy**.
    - Pluvicto was previously approved for this indication in patients who have been treated with ARPI therapy and have received prior taxane-based chemotherapy. **This approval expands the use of Pluvicto for earlier use before chemotherapy**.
- The approval of Pluvicto for the expanded indication was based on PSMAfore, a randomized, open-label study in 468 patients with progressive, PSMA-positive mCRPC. Patients were randomized to Pluvicto every 6 weeks for 6 doses or a change in ARPI. The major outcome measure was radiographic progression-free survival (rPFS). Additional efficacy measures were overall survival (OS) and overall response rate (ORR).
    - Median rPFS was 9.3 months with Pluvicto vs. 5.6 months with ARPI (hazard ratio 0.41, 95% CI: 0.29, 0.56; $p < 0.0001$).
    - The difference in median OS between the two groups was not significant.
    - The ORR was 49% (95% CI: 37, 61) with Pluvicto vs. 14% (95% CI: 7, 24) with ARPI.
- The recommended Pluvicto dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks for 6 doses, or until disease progression, or unacceptable toxicity.