Pluvicto approved for PSMA-positive metastatic castration-resistant prostate cancer

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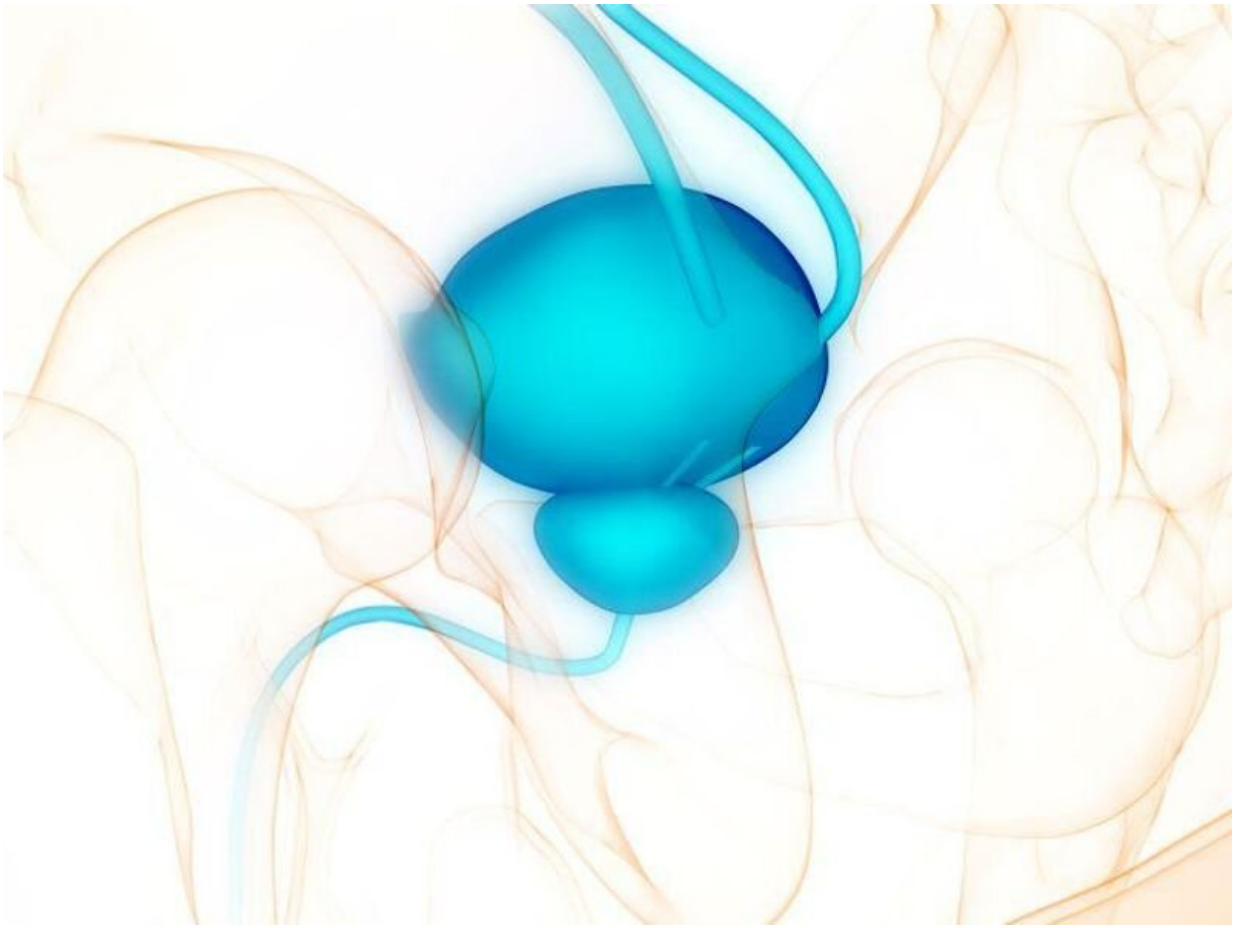

The U.S. Food and Drug Administration approved Pluvicto (lutetium Lu 177 vipivotide tetraxetan) for treatment of adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have received androgen receptor pathway inhibition and taxane-based chemotherapy. Simultaneously, the agency also approved the first radioactive diagnostic agent for patient selection in the use of a radioligand therapeutic agent, Locametz (gallium Ga 68 gozetotide), the agency announced March 23.

Pluvicto is indicated for patients with previously treated mCRPC. Patient selection should be done using the diagnostic agent Locametz or another approved PSMA-11 imaging agent for positron emission tomography of PSMA-positive lesions, defined as those with gallium Ga 68 gozetotide uptake greater than normal liver.

The approval was based on efficacy data from the VISION trial, a randomized, multicenter, open-label trial evaluating Pluvicto plus best standard of care (BSoC) versus BSoC alone in men with progressive, PSMA-positive mCRPC. All patients received a GnRH analog or had previous bilateral orchiectomy, and all had received at least one androgen receptor pathway inhibitor and one or two prior taxane-based chemotherapy regimens. Researchers randomly assigned 551 patients to Pluvicto 7.4 GBq (200 mCi) every six weeks for up to six doses plus BSoC and 280 patients to BSoC alone.

Pluvicto plus BSoC demonstrated a statistically significant improvement in overall survival versus BSoC alone (hazard ratio, 0.62; 95 percent confidence interval [CI], 0.52 to 0.74). Median overall survival was 15.3 months (95 percent CI, 14.2 to 16.9) for patients receiving Pluvicto plus BSoC and 11.3 months (95 percent CI, 9.8 to 13.5) for those receiving BSoC alone.

The most commonly reported adverse events with Pluvicto included

fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Patients receiving Pluvicto also commonly had decreased lymphocytes, hemoglobin, leukocytes, platelets, calcium, and sodium.

Approval was granted to Advanced Accelerator Applications USA Inc., a Novartis company.

More information: More Information