Targeted Radioligand Approved for Metastatic Prostate Cancer

A therapy that uses a ligand to deliver a therapeutic radioisotope to individual cancer cells throughout the body gained FDA approval for certain patients with metastatic prostate cancer. When the ligand binds with a cancer cell, the attached radiotherapeutic agent kills or interferes with the cell’s reproduction, as well as that of nearby cells.

Lutetium Lu 177 vipivotide tetraxetan (formerly called 177Lu-PSMA-617), marketed as Pluvicto, is an add-on injection therapy for patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have previously been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. Studies are underway to include patients earlier in treatment, according to a statement by manufacturer Advanced Accelerator Applications USA, Inc, a Novartis company.

The therapy is delivered by injection every 6 weeks for up to 6 doses. In a phase 3 study involving 831 patients, those receiving standard of care plus lutetium Lu 177 vipivotide tetraxetan had a significant reduction in risk of death with a median overall survival of 15.3 months compared with 11.3 months for the standard of care-only control group.

In a subgroup of 581 patients, imaging-positive-progress-free survival also was prolonged in the treatment group for a median 8.7 months compared with 3.4 months for the control group. These patients were randomized after a protocol change reduced dropouts in the control group, primarily from dissatisfaction, from 56% to 16.3%. Severe adverse events were more frequent in the treatment group, with grade 3 or higher events occurring in 52.7% of this group compared with 38% of the control group. However, quality of life mostly was not adversely affected as measured by a standardized assessment questionnaire.

The FDA also approved the first radioactive diagnostic agent for positron emission tomography of PSMA-positive lesions, including selecting patients for lutetium Lu 177 vipivotide tetraxetan therapy.

First Amphetamine Transdermal Patch Approved for ADHD

The FDA has approved the first amphetamine transdermal patch for treating attention-deficit/hyperactivity disorder (ADHD) among adults and children aged 6 years or older.

First Donepezil Transdermal Patch Approved for Alzheimer Disease

The first donepezil transdermal patch for treatment of mild, moderate, or severe Alzheimer disease-related dementia has been approved by the FDA.

Market as Adalicy, the donepezil transdermal delivery system is applied weekly to the back, thigh, or buttocks. It is available in 5-mg/d and 10-mg/d strengths, replacing oral donepezil at the same dosages. The system is designed to continuously deliver medication through the skin, maintaining a constant level needed for effective treatment. Transdermal delivery also may reduce the risk of adverse gastrointestinal effects associated with oral donepezil, according to a statement by manufacturer Corium, Inc, as well as ease administration for patients who have trouble swallowing or remembering to take a daily pill.

The donepezil transdermal delivery system was approved through FDA’s 505(b)(2) regulatory pathway, which allows developers to reference studies conducted by others rather than repeat them. Corium’s drug application included data from several clinical trials conducted by the company. According to the company news release, the transdermal system demonstrated bioequivalence to Aricept, the original oral preparation of donepezil, a cholinesterase inhibitor. Rollout is planned for early fall 2022. – Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.