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-based progression-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 radiotherapeutic agent for patient selection in the use of a radioligand therapeutic agent. Gallium Ga 68 gozetotide, marketed as Locametz, is a 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.

The dextroamphetamine patch, marketed as Velcrystm, is applied for up to 9 hours, takes effect after 2 hours, and remains effective for up to 12 hours. It is designed to give clinicians and patients more control over dosing time to better fit their schedules and optimize treatment benefits, according to a statement by manufacturer Noven Pharmaceuticals, Inc. The new patch is the second amphetamine transdermal patch for treating ADHD among adults and children aged 6 to 17 years, those treated with the dextroamphetamine patch met the primary end point of significant improvement compared with placebo-treated controls on a standardized rating of classroom impairment due to ADHD. It also met secondary end points for time from dosing to onset of effect and for performance on a test measuring ability to attend and initiate tasks.

The most common adverse effects observed among children were decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, blood pressure increase, and heart rate increase. The patch’s efficacy and safety for adults were established based on a comparable pharmacokinetic profile in adults and children and studies showing similarity to oral lisdexamfetamine, a stimulant marketed as Vyvanse.

Noven is preparing the patch’s commercial launch for the second half of 2022. It will be available in 4 strengths ranging from 4.5 mg to 18 mg, according to the company.

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.

Marketed as Adallity, 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 dosage. 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.