FDA Approves Immunotherapy for Endometrial Cancer with Specific Biomarker

New checkpoint inhibitor Jemperli is approved for cancers with deficient mismatch repair mechanism for fixing damaged DNA.

April 29, 2021 By Food and Drug Administration (FDA)

Today, the U.S. Food and Drug Administration granted accelerated approval to Jemperli (dostarlimab) for treating patients with recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing chemotherapy and whose cancers have a specific genetic feature known as dMMR [deficient mismatch repair] (which contain abnormalities that affect the proper repair of DNA inside the cell), as determined by an FDA-approved test.

“Today’s approval of Jemperli is evidence of the FDA’s progress in applying precision medicine to expand treatment options for patients with cancer,” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. “This immunotherapy was specifically studied to target dMMR endometrial cancer and leverages scientific knowledge surrounding the mechanism of immunotherapy response in this unmet medical need population.”

Endometrial cancer is the most common gynecologic malignancy in the United States and its prevalence is increasing. Approximately 75% of endometrial cancers are diagnosed at an early stage and are typically curable with surgery. However, women with advanced and recurrent endometrial cancer have limited therapeutic options following front-line standard treatment with a platinum-containing chemotherapeutic regimen. Approximately 25% to 30% of patients with advanced endometrial cancer have dMMR tumors.

Jemperli works by targeting the cellular pathway known as PD-1/PD-L1 (proteins found on the body’s immune cells and some cancer cells). Jemperli helps the body’s immune system in its fight against cancer cells by blocking this pathway.

The safety and efficacy of Jemperli was studied in a single-arm, multi-cohort clinical trial. Of the 71 patients with dMMR recurrent or advanced endometrial cancer who received Jemperli in the trial, 42.3% had a complete response (disappearance of tumor) or a partial response (shrinkage of

tumor) to treatment with Jemperli. For 93% of responders, the response lasted for six months or more.

Common side effects of Jemperli include fatigue, nausea, diarrhea, anemia and constipation. Jemperli can cause serious conditions known as immune-mediated side effects, including inflammation of healthy organs such as the lungs (pneumonitis), colon (colitis), liver (hepatitis), endocrine glands (endocrinopathies) and kidneys (nephritis).

Patients who experience severe or life-threatening infusion-related reactions should stop taking Jemperli. Women who are pregnant or breastfeeding should not take Jemperli because it may cause harm to a developing fetus or newborn baby. The safety and effectiveness of Jemperli in pediatric patients are not known.

Jemperli received Priority Review designation and Breakthrough Therapy designation for this indication. Priority Review designation directs overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

Jemperli was approved for this new indication using the Accelerated Approval pathway, under which the FDA may approve drugs for serious conditions where there is unmet medical need and a drug is shown to have certain effects that are reasonably likely to predict a clinical benefit to patients. Further clinical trials may be required to verify and describe anticipated clinical benefits of Jemperli and the sponsor is currently conducting these trials in additional patients with dMMR endometrial tumors.

The FDA granted approval to GlaxoSmithKline.

This news release was published by the Food and Drug Administration on April 22, 2021.
