FDA Approves Zepzelca for Metastatic Small-Cell Lung Cancer

Lurbinectedin shrank tumors in a third of people with this less common type of lung cancer.

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On June 15, the Food and Drug Administration (FDA) granted accelerated approval of Zepzelca (lurbinectedin) for the treatment of people with metastatic small-cell lung cancer (SCLC) whose disease has progressed during or after platinum-based chemotherapy. SCLC accounts for about 10% to 15% of lung cancer cases.

“Lurbinectedin is the first new drug approved for second-line treatment [of SCLC] since 1996,” Charles Rudin, MD, PhD, of Memorial Sloan Kettering Cancer Center in New York City said in a press release. “SCLC remains a major unmet medical need. Many of us in the oncology community will welcome lurbinectedin as a new standard option for patients with recurrent SCLC.”

Zepzelca, from Jazz Pharmaceuticals and PharmaMar, is an alkylating agent that binds to DNA and interferes with transcription factors that play a role in cancer cell growth. The drug, derived from a compound isolated from sea squirts, also inhibits the activity of certain immune cells and the production of cytokines that spur tumor growth.

The accelerated approval was based on findings from a single-arm Phase II basket trial that enrolled people with a variety of solid tumors.

The study included 105 adults with SCLC at 26 hospitals in the United States and Europe. Most (70%) were classified as having extensive-stage cancer, usually spread to the lymph nodes, liver or adrenal glands; however, those with brain metastasis were excluded. All had disease progression after treatment with platinum-based chemotherapy. More than 90% had received just one prior line of treatment and 7% had received two lines.

Participants received Zepzelca monotherapy by intravenous infusion for one hour every three weeks until they experienced disease progression or unacceptable side effects. They were treated for a median of four cycles.

As reported at last year’s American Society of Clinical Oncology annual meeting and in a recent issue of The Lancet Oncology, during a median follow-up period of 17 months, just over a third of participants experienced partial tumor shrinkage, for an overall response rate of 35%. The median

duration of response was 5.3 months.

The median progression-free survival duration, meaning patients were alive without worsening disease, was 3.5 months, and 33% were still free of progression at six months. The median overall survival duration was 9.3 months; 67% were still alive at six months and 34% were alive at 12 months.

Therapies that receive accelerated approval based on overall response rates are expected to undergo further testing in larger randomized trials to confirm clinical benefits, and the FDA can rescind approval if they don't measure up.

Treatment with Zepzelca is generally safe, though side effects are common. In the Phase II study, a quarter of participants reduced their doses due to an adverse reaction but only two (2%) stopped treatment for this reason.

The most common adverse events include fatigue, nausea, vomiting, decreased appetite, diarrhea, constipation, muscle or joint pain, cough and shortness of breath. The most common laboratory abnormalities include increased ALT and AST liver enzymes, increased creatinine (a biomarker of kidney function) and elevated blood glucose. Zepzelca can cause depletion of red blood cells, white blood cells and platelets, which can lead to fatigue, increased susceptibility to infections and easy bleeding.

"Lurbinectedin was active as second-line therapy for SCLC in terms of overall response and had an acceptable and manageable safety profile," the study investigators concluded. "Lurbinectedin could represent a potential new treatment for patients with SCLC, who have few options especially in the event of a relapse."

Zepzelca will be available in early July, according to a press release from Jazz, which will market the new drug in the United States.

"In addition to the physical toll it takes on patients, a relapse of SCLC also takes a mental and emotional toll on the entire family," Andrea Ferris, president and chief executive officer of LUNGevity, said in the Jazz press release. "The availability of Zepzelca presents new hope for patients and their loved ones, and we're eager to see its impact on the SCLC community."

Click here for full prescribing information for Zepzelca.
Click here to learn more about lung cancer.

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