HEM/ONC News

By Devon Schuyler

Tepotinib Receives Accelerated Approval for Metastatic Non–Small Cell Lung Cancer

On February 3, the US Food and Drug Administration (FDA) granted accelerated approval to tepotinib (Tepmetko, EMD Serono) for adults with metastatic non–small cell lung cancer (NSCLC) harboring *MET* exon 14–skipping alterations.

Approval was based on the VISION trial, a multicenter, nonrandomized, open-label, multicohort study enrolling 152 patients who had advanced or metastatic NSCLC with *MET* exon 14–skipping alterations. Patients received 450 mg of tepotinib orally once daily until disease progression or unacceptable toxicity.

The overall response rate (ORR) was 43% among the 69 treatment-naive patients, with a median duration of response (DOR) of 10.8 months. The ORR also was 43% among the 83 previously treated patients, with a median DOR of 11.1 months.

The most common adverse reactions were edema, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea. Tepotinib can also cause interstitial lung disease, hepatotoxicity, and embryo-fetal toxicity. Tepotinib should be taken with food.

Umbralisib Receives Accelerated Approval for Marginal Zone Lymphoma and Follicular Lymphoma

On February 5, the FDA granted accelerated approval to umbralisib (Ukoniq, TG Therapeutics) for adults with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 prior anti-CD20–based regimen, and for adults with relapsed or refractory follicular lymphoma (FL) who have received at least 3 prior lines of systemic therapy. Umbralisib is a dual inhibitor of PI3K-delta and CK1-epsilon.

Approval was based on 2 single-arm cohorts of the open-label UTX-TGR-205 trial: 69 patients with MZL who had received at least 1 prior therapy, including an anti-CD20–containing regimen, and 117 patients with FL who had received at least 2 prior systemic therapies. Patients received 800 mg of umbralisib orally once daily until disease progression or unacceptable toxicity.

Among the patients with MZL, the ORR was 49%, with a complete response (CR) achieved in 16%; the median DOR was not reached. Among the patients with FL, the ORR was 43%, with a CR achieved in 3%; the median DOR was 11.1 months.

The most common adverse reactions were increased creatinine, diarrhea-colitis, fatigue, nausea, neutropenia, transaminase elevation, musculoskeletal pain, anemia, thrombocytopenia, upper respiratory tract infection, vomiting, abdominal pain, decreased appetite, and rash. Serious adverse reactions occurred in 18% of patients.

Umbralisib was granted priority review for the MZL indication, and orphan drug designation was granted for the treatment of MZL and FL.

Lisocabtagene Maraleucel Approved for Use in Relapsed/Refractory Large B-Cell Lymphoma

On February 5, the FDA granted approval to lisocabtagene maraleucel (Breyanzi, Bristol Myers Squibb) for the treatment of certain patients with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy. Lisocabtagene maraleucel, which is a chimeric antigen receptor T-cell therapy, is not indicated for the treatment of patients with primary central nervous system lymphoma.

The approval was based on a multicenter clinical trial of more than 250 adults with relapsed or refractory large B-cell lymphoma. The complete remission rate after treatment with lisocabtagene maraleucel was 54%.

The labeling carries a boxed warning about cytokine release syndrome (CRS), which can cause neurologic toxicities and be life-threatening. Other side effects include hypersensitivity reactions, serious infections, low blood cell counts, and a weakened immune system. Because of the risk for CRS and neurologic toxicities, lisocabtagene maraleucel is approved with a risk evaluation and mitigation strategy that includes a requirement that health care facilities dispensing lisocabtagene maraleucel be specially certified.

New in Nonfiction

Board member John Marshall, MD, and his wife, Liza Marshall, have written *Off Our Chests: A Candid Tour Through the World of Cancer*. In this book, they describe their experience with Liza's diagnosis of stage III breast cancer at age 43, her treatment at the cancer center where her husband works as the chief of hematology and oncology, and how John's new role as caregiver and worried husband gave him a new understanding of the disease and of being a physician. From Ideapress Publishing, available April 6.