HEM/ONC News

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Abemaciclib Approved in HR-Positive, HER2-Negative Advanced or Metastatic Breast Cancer

On September 28, the US Food and Drug Administration (FDA) approved abemaciclib (Verzenio, Lilly) as a treatment for certain advanced or metastatic breast cancers. Like the agents palbociclib (Ibrance, Pfizer) and ribociclib (Kisqali, Novartis), abemaciclib is an inhibitor of cyclin-dependent kinases 4 and 6.

Abemaciclib is indicated for adults with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative advanced or metastatic breast cancer that has progressed despite endocrine therapy. It may be given alone or in combination with fulvestrant (Faslodex, AstraZeneca).

The combination of abemaciclib and fulvestrant was studied in a randomized trial of 669 patients with HR-positive, HER2-negative breast cancer that had progressed after endocrine therapy. Patients did not receive chemotherapy after the cancer had metastasized. The median progression-free survival was 16.4 months for people who received abemaciclib/fulvestrant vs 9.3 months for those who received fulvestrant alone.

Abemaciclib alone was studied in a single-arm trial of 132 patients with HR-positive, HER2-negative breast cancer that had progressed after endocrine therapy and chemotherapy administered after the cancer had metastasized. The objective response rate for abemaciclib was 19.7%, with a median duration of response of 8.6 months.

Common side effects of abemaciclib include diarrhea, neutropenia, leukopenia, nausea, abdominal pain, infections, fatigue, anemia, decreased appetite, vomiting, and headache. Serious side effects include diarrhea, neutropenia, elevated liver function tests, and deep venous thrombosis/pulmonary embolism. Women who are pregnant should not take abemaciclib.

Abemaciclib received priority review and breakthrough therapy designations.

Copanlisib Approved for Adults With Relapsed Follicular Lymphoma

The FDA granted accelerated approval to copanlisib (Aliqopa, Bayer HealthCare) on September 14 for the treatment of adults with relapsed follicular lymphoma who have received at least 2 prior systemic therapies. Copanlisib is an inhibitor of phosphoinositide 3-kinase.

The approval of copanlisib was based on data from a single-arm trial that included 104 patients with follicular B-cell non-Hodgkin lymphoma whose disease had relapsed after at least 2 prior systemic treatments. The trial found that 59% of patients had an objective response, which lasted for a median of 12.2 months.

Common side effects of copanlisib include hyperglycemia, diarrhea, decreased general strength and energy, hypertension, leukopenia, neutropenia, nausea, lower respiratory tract infections, and thrombocytopenia. Serious side effects include infections, hyperglycemia, hypertension, noninfectious pneumonitis, neutropenia, and severe skin reactions. Women who are pregnant or breastfeeding should not take copanlisib.

The FDA granted copanlisib priority review and orphan drug designations. Further clinical trials are required to confirm the clinical benefit of this agent.

Nivolumab Provides Long-term Benefit to Patients With NSCLC

The FDA approved the use of nivolumab (Opdivo, Bristol-Myers Squibb) for patients with previously treated squamous and nonsquamous advanced non–small cell lung cancer (NSCLC) on the basis of results of the CheckMate 017 and CheckMate 057 trials. Now, an analysis of these trials by Dr Leora Horn and colleagues, published online October 12 in the *Journal of Clinical Oncology*, finds that nivolumab provides long-term clinical benefit and is better tolerated than docetaxel.

The analysis, in which the minimum follow-up for survival was 24.2 months, found that overall survival (OS) at 2 years was significantly higher with nivolumab than with docetaxel among the 272 patients with squamous NSCLC (23% vs 8%, respectively) and the 582 patients with nonsquamous NSCLC (29% vs 16%, respectively). Nivolumab also led to durable responses; 10 of the 27 responders with squamous NSCLC and 19 of the 56 responders with nonsquamous NSCLC continued to have responses at long-term follow-up. No patient in the docetaxel group had an ongoing response. In addition, nivolumab prolonged OS not only in those who responded to the drug but also in those who had stable disease.

A pooled analysis revealed that median OS was significantly better with nivolumab (11.1 months) than with docetaxel (8.1 months). Although patients with at least 50% expression of programmed death ligand 1 (PD-L1) had the greatest OS benefit with nivolumab (hazard ratio, 0.42), those with less than 1% expression of PD-L1 also benefited (hazard ratio, 0.78).

The pooled analysis did not reveal any new safety concerns with nivolumab, which continued to be associated with fewer adverse events than docetaxel.