FDA Approves New Immunotherapy for Advanced Liver Cancer

Imjudo plus Imfinzi improved overall survival compared with standard targeted therapy for hepatocellular carcinoma.

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On October 24, the Food and Drug Administration (FDA) approved a new checkpoint inhibitor, Imjudo (tremelimumab), for use in a combination immunotherapy regimen for adults with inoperable hepatocellular carcinoma (HCC), the most common type of liver cancer.

Over years or decades, hepatitis B, hepatitis C, fatty liver disease, heavy alcohol use or other causes can lead to serious complications, including liver cirrhosis, liver cancer and the need for a liver transplant. Liver cancer is often diagnosed late, and it is difficult to treat, making it one of the fastest-rising causes of cancer death in the United States.

Imjudo, a new monoclonal antibody from AstraZeneca, was approved for use with Imfinzi (durvalumab), a different type of checkpoint blocker. It is the second approved drug, after Yervoy (ipilimumab), that targets CTLA-4, a receptor protein that suppresses immune response by inhibiting T-cell multiplication. Most approved checkpoint inhibitors, including Imfinzi, target PD-1 or PD-L1, which together act as a brake on T cells; these drugs restore T-cell activity against cancer cells. A similar checkpoint inhibitor combination, Yervoy plus Opdivo (nivolumab), was previously approved for HCC treatment.

The new approval was based on results from the Phase III HIMALAYA trial (NCT03298451), which included more than 1,000 people with Stage III or IV unresectable HCC who had not used prior systemic therapies and were not eligible for local therapies. They were randomly assigned to receive a single priming dose of Imjudo plus Imfinzi administered by IV infusion every four weeks (dubbed the STRIDE regimen), Imfinzi alone or the oral targeted therapy Nexavar (sorafenib).

As reported at this year's ASCO Gastrointestinal Cancers Symposium and published in New England Journal of Medicine Evidence, people treated with Imjudo plus Imfinzi saw a significant improvement in overall survival, with a 22% lower risk of death compared with Nexavar. Imfinzi alone was deemed noninferior, meaning it worked at least as well as Nexavar. After three years, 31% of people who used Imjudo plus Imfinzi, 25% who used Imfinzi alone and 20% who used Nexavar were still alive. The overall response rate, meaning tumor shrinkage, was 20% for Imjudo plus Imfinzi versus just 5% for Nexavar.

Treatment with Imjudo plus Imfinzi is generally safe, but side effects are common. The most frequently reported adverse reactions are rash, diarrhea, fatigue, itching, muscle and joint pain and abdominal pain. In addition, checkpoint inhibitors can cause immune-related adverse events. While restoring immune responses against cancer, these drugs can also cause the immune system to attack healthy tissue, leading to excessive inflammation of organs including the lungs, intestines, liver, kidneys and endocrine glands.

“Patients with unresectable liver cancer are in need of well-tolerated treatments that can meaningfully extend overall survival,” lead study investigator Ghassan Abou-Alfa, MD, of Memorial Sloan Kettering Cancer Center, said in an AstraZeneca press release. “In addition to this regimen demonstrating a favorable three-year survival rate in the HIMALAYA trial, safety data showed no increase in severe liver toxicity or bleeding risk for the combination, important factors for patients with liver cancer who also have advanced liver disease.”

This week’s FDA action was the first approval for Imjudo; Imfinzi was previously approved for several types of cancer. The Imjudo plus Imfinzi combination is also being studied for non-small-cell lung cancer (NSCLC), harder-to-treat small-cell lung cancer, bladder cancer and other tumor types. Some previous studies failed to show improved survival in people using the combination. However, results from the Phase III POSEIDON trial, presented at the European Society of Medical Oncology Congress last month, showed that Imjudo plus Imfinzi and chemotherapy prolonged survival compared with chemotherapy alone for people with metastatic NSCLC. Switching to the STRIDE (Single Tremelimumab Regular Interval Durvalumab) dosing schedule appears to have improved outcomes.

Click here for full prescribing information for Imjudo.

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