FDA Grants Priority Review to Keytruda-Chemo Combo for Metastatic NSCLC

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The U.S. Food and Drug Administration (FDA) has agreed to review a combination of Keytruda (pembrolizumab) and chemotherapy as first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC).

Merck's supplemental Biologics License Application (sBLA) received priority review and a decision is expected by Oct. 30.

The decision follows the acceptance of a similar application by the European Medicines Agency (EMA), requesting Keytruda's approval in combination with Alimta (pemetrexed) or platinum-based chemotherapy as the first-line treatment for NSCLC patients.

"Keytruda has already been established as an important treatment option for non-small cell lung cancer in the first-line setting, and with our broad development program in lung cancer, we are committed to improving survival for as many patients as we can," Roy Baynes, MD, said in a press release. Baynes is senior vice president and head of global clinical development, and chief medical officer, Merck Research Laboratories. (Merck is known as MSD outside of the United States and Canada.)

"We are pleased that our application for squamous cell carcinoma — a historically challenging-to-treat disease — is under priority review with the FDA," he said.

The FDA's decision was based on data from an ongoing Phase 3 trial, called KEYNOTE-407 (NCT02775435).

The trial, which is still recruiting volunteers, is testing if adding Keytruda to standard chemotherapy — Paraplatin (carboplatin), and either Taxol (paclitaxel) every three weeks, or weekly Abraxane (nab-paclitaxel) — extends the time a patient lives without disease worsening and improves overall survival.

Results from the first 204 patients included in the study showed that 58.4% of patients receiving the combination experienced a reduction in tumor size, compared to 35% of those receiving chemo alone.

Patients had received the therapy for a median time of 7.7 months. The response lasted more then six months in 65.8% of patients receiving the combination, compared to 45.6% in the chemotherapy group.

The findings were presented recently during the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting, in Chicago.

The research was titled "Phase 3 study of carboplatin-paclitaxel/nab-paclitaxel (Chemotherapytherapy) with or without Keytrudalizumab (Keytruda) for patients (Patients) with metastatic squamous (Sq) non-small cell lung cancer (NSCLC)."

The PD-1 receptor on immune cells usually acts as an “off switch,” keeping them from being overly active and attacking a person’s own tissues and cells. But tumor cells can take advantage of this mechanism, producing large amounts of the PD-L1 ligand, which helps them evade immune surveillance.

Keytruda is an immune checkpoint inhibitor designed to prevent this from happening, restoring the immune system’s ability to mount an attack against tumor cells.