BioSpectrum the business of Bio & Health Sciences

FDA approves expanded Monotherapy label for Merck's Keytruda

12 April 2019 | News

In the trial, KEYTRUDA monotherapy demonstrated a statistically significant improvement in OS compared with chemotherapy alone in patients whose tumors expressed PD-L1 with a TPS ?50%, with a TPS ?20%, and then in the entire study population (TPS ?1%).

Merck known as MSD outside the United States and Canada has announced that the U.S. Food and Drug Administration (FDA) has approved an expanded label for KEYTRUDA, Merck's anti-PD-1 therapy, as monotherapy for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ?1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. The approval is based on results from the Phase 3 KEYNOTE-042 trial, in which overall survival (OS) was sequentially tested as part of a pre-specified analysis plan. In the trial, KEYTRUDA monotherapy demonstrated a statistically significant improvement in OS compared with chemotherapy alone in patients whose tumors expressed PD-L1 with a TPS ?50%, with a TPS ?20%, and then in the entire study population (TPS ?1%).

"This expanded first-line indication now makes KEYTRUDA monotherapy an option for more patients with non-small cell lung cancer, including those for whom combination therapy may not be appropriate," said Dr. Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories.

Immune-mediated adverse reactions, which may be severe or fatal, can occur with KEYTRUDA, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, severe skin reactions, solid organ transplant rejection, and complications of allogeneic hematopoietic stem cell transplantation (HSCT). Based on the severity of the adverse reaction, KEYTRUDA should be withheld or discontinued and corticosteroids administered if appropriate. KEYTRUDA can also cause severe or life-threatening infusion-related reactions. Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. For more information, see "Selected Important Safety Information" below.

“The KEYNOTE-042 trial demonstrated a survival benefit with KEYTRUDA monotherapy across histologies in certain patients with stage III or metastatic non-small cell lung cancer whose tumors expressed PD-L1 in at least 1% of tumor cells,” said Dr. Gilberto Lopes, associate director for global oncology at the Sylvester Comprehensive Cancer Center at the University of Miami. “As a practicing oncologist, having additional options available for patients is important in the rapidly evolving treatment landscape for lung cancer, which remains the leading cause of cancer death in the United States.”

KEYTRUDA was the first anti-PD-1 therapy in metastatic NSCLC approved in the first-line setting as combination therapy or monotherapy.