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ASIA EDITION

Merck’s KEYTRUDA (pembrolizumab) approved in China for ESCC Tumors

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KEYTRUDA Is now approved across Five indications for Three different types of Cancer in China and Is First Anti-PD-1 therapy approved for Esophageal Cancer

Merck, known as MSD outside the United States and Canada, on 22 June 2020 announced that KEYTRUDA, Merck’s anti-PD-1 therapy, has been approved by the National Medical Products Administration (NMPA) in China as monotherapy for the treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ?10) as determined by a fully validated test, following failure of one prior line of systemic therapy. This new indication was granted full approval based on the overall survival (OS) findings from the global Phase 3 KEYNOTE-181 trial, including data from an extension of the global study in Chinese patients. With this new approval, KEYTRUDA is now approved for five indications across three different types of cancer in China, including as a first-line treatment for appropriate patients with advanced non-small cell lung cancer (monotherapy and in combination with chemotherapy) and as a second-line treatment for advanced melanoma. The U.S. Food and Drug Administration approval in July 2019 was based upon the global KEYNOTE-181 trial.

“In China, more than 90% of esophageal cancers are squamous cell carcinomas, and patients with advanced types of this disease face a poor prognosis and have few treatment options,” said Dr. Shen Lin, vice president of Clinical Oncology at Beijing Cancer Hospital and Peking University and deputy director of Beijing Institute for Cancer Research. “This approval represents an important advancement for certain patients with esophageal squamous cell carcinoma who now have an immunotherapy treatment option.”

In the KEYNOTE-181 trial, an improvement in OS was observed in patients who were treated with KEYTRUDA monotherapy compared with chemotherapy in previously treated patients with recurrent or metastatic ESCC whose tumors expressed PD-L1 (CPS ?10) (HR=0.64 [95% CI, 0.46-0.90]). The median OS was 10.3 months for KEYTRUDA compared with 6.7 months for chemotherapy.

In the extension of the KEYNOTE-181 study in Chinese patients, consistent with the KEYNOTE-181 global study, there was an improvement in OS for patients who were treated with KEYTRUDA monotherapy compared with chemotherapy in previously treated patients with recurrent or metastatic ESCC whose tumors expressed PD-L1 (CPS ?10) (HR=0.38 [95% CI, 0.19-0.77]). The median OS was 12.0 months for KEYTRUDA compared with 5.4 months for chemotherapy.

“In China, there is a high incidence of esophageal cancer, and it is the fourth leading cause of cancer-related death,” said Dr.

Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories. “This approval for KEYTRUDA provides an important new option for certain patients with esophageal carcinoma in China, where there have been few treatment advances in recent years.”

“The approval for patients with second-line esophageal squamous cell carcinoma marks the fifth indication for KEYTRUDA across three different types of cancer in China,” said Joseph Romanelli, president of MSD in China. “With each approval, we’ve made steady progress to ensure patients have access to KEYTRUDA, and we will ensure the same for patients who are impacted by esophageal squamous cell carcinoma.”