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ASIA EDITION

Merck’s Keytruda gets approval in China for advanced melanoma

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Melanoma is one of the fastest growing malignant cancers in China, increasing at an annual rate of 3-5 percent, which makes it one of the deadliest diseases in the country. Research data has shown that once the disease metastasizes, the five-year survival rate for metastatic melanoma in Chinese patients is only 4.6 percent.

Merck known as MSD outside the United States and Canada has announced that KEYTRUDA Merck’s anti-PD-1 therapy, has been approved by the China National Drug Administration (CNDA) for the treatment of adult patients with unresectable or metastatic melanoma following failure of one prior line of therapy. This is the first and only approval of an anti-PD-1 therapy for advanced melanoma in China.

“Over the past decades, we have had limited effective options in the treatment of patients with advanced melanoma,” Professor Jun Guo, M.D., Ph.D, director of the Department of Melanoma & Renal Cancer, Peking University Cancer Hospital and Institute Secretary-General of the Chinese Society of Clinical Oncology, primary investigator, KEYNOTE-151. “Advanced melanoma is one of the cancers that has been most responsive to immunotherapy, and outside of China, anti-PD-1 therapies such as pembrolizumab have become the standard therapy for this disease. With the approval of pembrolizumab in China, the treatment of advanced melanoma will now be aligned with international standards.”

The approval of KEYTRUDA in China was based on overall response rate (ORR) data from the Phase 1b KEYNOTE-151 study, which evaluated KEYTRUDA monotherapy in Chinese patients with previously treated locally advanced or metastatic melanoma who received one prior line of systemic therapy. In 2018, the CNDA granted priority review status to KEYTRUDA, which accelerated the approval process by allowing for simultaneous clinical validation for the first time – creating an industry leading approval turnaround time for imported cancer medicine in China.

“Merck is committed to bringing new treatment advances, like KEYTRUDA, to cancer patients in China,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “The approval of KEYTRUDA in China, for this first indication, was made possible through extensive collaborative effort with the Chinese patients and investigators who participated in KEYNOTE-151, as well as the regulatory and government authorities who prioritized this filing. We appreciate their commitment to bringing forward the first anti-PD-1 therapy for

advanced melanoma in China."

"The approval of our anti-PD-1 therapy reflects the Chinese government's strong commitment to expedite the introduction of innovative therapies to Chinese patients," said Joseph Romanelli, president of MSD China. "The approval of KEYTRUDA in advanced melanoma marks the sixth new product approval for MSD China in 2018. We are encouraged that our scientific advancements are leading to new options for patients and their families."