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FDA grants priority review to Merck’s application for KEYTRUDA in SCLC

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This acceptance marks the first U.S. application for KEYTRUDA in SCLC and demonstrates Merck’s commitment to bringing forward new treatment options for patients with historically difficult-to-treat cancers, like SCLC.

Merck announced that the U.S. Food and Drug Administration (FDA) has accepted and granted priority review for a new supplemental Biologics License Application (sBLA) for KEYTRUDA, Merck’s anti-PD-1 therapy, as monotherapy for the treatment of patients with advanced small cell lung cancer (SCLC) whose disease has progressed after two or more lines of prior therapy.

This sBLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA has set a Prescription Drug User Fee Act (PDUFA), or target action, date of June 17, 2019.

“There is a significant need for new treatment options for small cell lung cancer, which has a five-year survival rate of only six percent overall,” said Dr. Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories. “KEYTRUDA has already been established as an important treatment option for many patients with advanced non-small cell lung cancer and this acceptance provides an opportunity to potentially benefit even more patients.”

This acceptance marks the first U.S. application for KEYTRUDA in SCLC and demonstrates Merck’s commitment to bringing forward new treatment options for patients with historically difficult-to-treat cancers, like SCLC. As part of our broad clinical development in lung cancer, KEYTRUDA is being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.