Keytruda® (pembrolizumab) – Indication withdrawal

- On March 1, 2021, Merck announced the voluntary withdrawal of the Keytruda (pembrolizumab) indication for treatment of patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

- The withdrawal of this indication was done in consultation with the FDA, and Merck is working to complete this process over the coming weeks. This decision does not affect other indications for Keytruda.

    — Refer to the Keytruda drug label for information regarding its other indications.

- Keytruda was granted accelerated approval for SCLC in June 2019 based on tumor response rate and durability of response data from KEYNOTE-158 and KEYNOTE-028. Continued approval for this indication was contingent upon completion of the post-marketing requirement establishing superiority of Keytruda as determined by overall survival (OS). As announced in January 2020, KEYNOTE-604, the confirmatory Phase 3 trial for this indication, met one of its dual primary endpoints of progression-free survival but did not reach statistical significance for the other primary endpoint of OS.

- Merck is notifying health care professionals about this withdrawal. Patients being treated with Keytruda for their metastatic SCLC should discuss their care with their health care provider.

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