

## Keytruda® (pembrolizumab) - New indication

- On January 27, 2023, Merck announced the FDA approval of Keytruda (pembrolizumab), as a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA non-small cell lung cancer (NSCLC).
- This approval marks the fifth indication for Keytruda-based regimens in NSCLC and overall, this is the 34<sup>th</sup> indication for Keytruda. Refer to the Keytruda drug label for a complete list of indications and uses.
- The approval of Keytruda for the new indication was based on KEYNOTE-091, a randomized, triple-blind, placebo-controlled study in 1177 patients with completely resected stage IB (T2a ≥4 cm), II, or IIIA NSCLC. Adjuvant chemotherapy up to 4 cycles was optional. Patients were randomized to receive Keytruda or placebo every 3 weeks. Treatment continued until disease recurrence as determined by the investigator, unacceptable toxicity, or up to one year. The major outcome measure was disease-free survival (DFS).
  - The trial met its primary endpoint, demonstrating a statistically significant improvement in DFS in the overall population for patients randomized to the Keytruda arm compared to patients randomized to the placebo arm.
  - In an exploratory subgroup analysis of the 167 patients (14%) who did not receive adjuvant chemotherapy, the DFS hazard ratio (HR) was 1.25 (95% CI: 0.76, 2.05).
  - In patients who did receive adjuvant chemotherapy, median DFS was 58.7 months and 34.9 months for Keytruda and placebo, respectively (HR 0.73, 95% CI: 0.60, 0.89).
- The recommended dose of Keytruda for the adjuvant treatment of NSCLC is 200 mg every 3
  weeks or 400 mg every 6 weeks, until disease recurrence, unacceptable toxicity, or up to 12
  months.
  - Refer to the Keytruda drug label for dosing for all its other indications.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.