



## Libtayo® (cemiplimab-rwlc) – New indication

- On February 22, 2021, [Regeneron announced](#) the FDA approval of [Libtayo \(cemiplimab-rwlc\)](#), for the first-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS]  $\geq$  50%) as determined by an FDA-approved test with no EGFR, ALK or ROS1 aberrations, and is:
  - Locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
  - Metastatic.
- Libtayo is also approved for cutaneous squamous cell carcinoma and basal cell carcinoma.
- The approval of Libtayo for the new indication was based on Study 1624, a randomized, open-label, active-controlled study in 710 patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation, or with metastatic NSCLC. Patients were randomized to receive Libtayo every 3 weeks for up to 108 weeks or a platinum-doublet chemotherapy regimen for 4 to 6 cycles followed by optional pemetrexed maintenance for patients with nonsquamous histology who received a pemetrexed containing regimen. The major efficacy outcome measures were overall survival (OS) and progression-free survival (PFS). An additional efficacy outcome measure was overall response rate (ORR).
  - Median OS was 22.1 months for Libtayo vs. 14.3 months for chemotherapy (hazard ratio [HR] 0.68, 95% CI: 0.53, 0.87;  $p = 0.0022$ ).
  - Median PFS 6.2 months for Libtayo vs. 5.6 months for chemotherapy (HR 0.59, 95% CI: 0.49, 0.72;  $p < 0.0001$ ).
  - ORR was 37% (95% CI: 32, 42) for Libtayo vs. 21% (95% CI: 17, 25) for chemotherapy. Median duration of response was 21.0 months (range 1.9+, 23.3+) and 6.0 months (range 1.3+, 16.5+), respectfully.
- The recommended dosage of Libtayo for all indications is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.
  - For NSCLC, patients should be selected based on PD-L1 expression on tumor cells. Information on FDA-approved tests for the detection of PD-L1 expression is available at: <http://www.fda.gov/CompanionDiagnostics>.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](http://optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.