Libtayo® (cemiplimab-rwlc) – Expanded indication

- On November 8, 2022, Regeneron announced the FDA approval of Libtayo (cemiplimab-rwlc), in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) 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 as a single-agent for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 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.
- In addition to NSCLC, Libtayo is also approved for treatment of cutaneous squamous cell carcinoma and basal cell carcinoma.
- The approval of Libtayo for the expanded indication was based on a randomized, double-blind, active-controlled study in 466 patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation or with metastatic NSCLC who had not previously received systemic treatment for metastatic NSCLC. Patients were randomized to Libtayo in combination with a physician's choice of platinum-doublet chemotherapy (Libtayo combination), compared to platinum-doublet chemotherapy alone. The major outcome measure was overall survival (OS). Additional efficacy outcome measures were progression-free survival (PFS) and overall response rate (ORR).
    - Median OS was 21.9 months with Libtayo combination vs. 13.0 months with chemotherapy alone (hazard ratio [HR] 0.71, 95% CI: 0.53, 0.93; p = 0.0140).
    - Median PFS was 8.2 months with Libtayo combination vs. 5.0 months with chemotherapy alone (HR 0.56, 95% CI: 0.44, 0.70; p < 0.0001).
    - The ORR was 43% (95% CI: 38, 49) with Libtayo combination and 23% (95% CI: 16, 30) with chemotherapy alone (p < 0.0001).
- The most common adverse reactions (≥ 15%) with Libtayo use in combination with platinum-based chemotherapy were alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite.
- The recommended dosage of Libtayo for all its uses is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.
    - Refer to the drug labels for the agents administered in combination with Libtayo for recommended dosing information, as appropriate