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] ≥ 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.