Clinical Trials1,2,3

**Keytruda versus Libtayo® no head to head trial but compared evidence:**

In patients with NSCLC who have high PD-L1 expression and no genomic aberrations, cemiplimab may produce more favorable outcomes than pembrolizumab, according to the findings of the meta-analysis. Although the OS remained unchanged, cemiplimab exhibited substantial improvements in PFS and ORR. The safety profiles of both medications were similar.

**Keytruda versus Libtayo® cost analysis:**

According to the findings, Cemiplimab appears to be a cost-effective option for advanced cutaneous squamous cell carcinoma (CSCC) compared to pembrolizumab.

**Cemiplimab Plus Chemotherapy Versus Chemotherapy Alone in Advanced NSCLC: Chemotherapy Alone in Advanced NSCLC: 2-Year Follow-Up From the Phase 3 EMPOWER-Lung 3 Part 2 Trial:**

At the final analysis following the study protocol, which included a 28.4-month follow-up, the EMPOWER-Lung 3 study consistently showed that combining cemiplimab with chemotherapy provides benefits over chemotherapy alone for patients with advanced non-small cell lung cancer (NSCLC), whether squamous or nonsquamous, across various levels of programmed death-ligand 1.

Indications4,5

* **Non-Small Cell Lung (NSCLC)**
  + in combination with platinum‐based chemotherapy for the first‐line treatment
  + as single agent for the first-line treatment
* **Basal Cell Carcinoma (BCC)**
* **Cutaneous Squamous Cell Carcinoma (CSCC)**

Dosage and Administration4,5

Administer by intravenous infusion over 30 minutes through an intravenous line containing a sterile, in-line or add-on 0.2-micron to 5-micron filter.

* **NSCLC:** 350 mg every 3 weeks until disease progression or unacceptable toxicity.
* **CSCC and BCCC:** 350 mg every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months.

Dosage Forms and Strengths4,5

* **Injection:** 350 mg/7 mL (50 mg/mL) solution in a single-dose vial.

Preparation4,5

* Withdraw 7 mL from a vial and dilute with NS or D5W to final concentration between 1 to 20 mg/mL.
* Do not shake; gently invert to mix diluted solution.
* Discard any unused medicinal product or waste material.

Storage4,5

* Store at room temperature up to 25°C (77°F) for no more than 8 hours from the time of preparation to the end of the infusion or at 2°C to 8°C (36°F to 46°F) for no more than 24 hours from the time of preparation to the end of infusion.
* Allow the diluted solution to come to room temperature prior to administration.
* Do not freeze.
* Store in the original carton.
* protect from light.

Contraindications4,5

There are no contraindications.

There are no contraindications.

Warnings and Precautions4,5

* **Immune-Mediated Adverse Reactions:** May be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune mediated nephritis and renal dysfunction, and solid organ transplant rejection.
* **Infusion-Related Reactions:** Interrupt, slow the rate of infusion, or permanently discontinue based on severity of reaction.
* **Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT):** Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.
* **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.

Adverse Reactions4,5

* **When used as a Single Agent:** 
  + (≥15%) are fatigue, musculoskeletal pain, rash, diarrhea, and anemia.
* **When used in Combination with Platinum-based Chemotherapy:**
  + (≥15%) are alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite.

Special Populations4,5

* **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of Libtayo®.
  + **Females and males of reproductive potential**: Verify pregnancy status in females of reproductive potential prior to initiating Libtayo®.

References:

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2. Paul E, Konidaris G, Cope S, et al. Cost-effectiveness analysis of cemiplimab vs pembrolizumab for treatment of advanced cutaneous squamous cell carcinoma. *J Manag Care Spec Pharm*. 2021;27(11):1513-1525. doi:10.18553/jmcp.2021.21164
3. Makharadze T, Gogishvili M, Melkadze T, et al. Cemiplimab Plus Chemotherapy Versus Chemotherapy Alone in Advanced NSCLC: 2-Year Follow-Up From the Phase 3 EMPOWER-Lung 3 Part 2 Trial [published correction appears in J Thorac Oncol. 2023 Oct 12;:]. *J Thorac Oncol*. 2023;18(6):755-768. doi:10.1016/j.jtho.2023.03.008
4. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.
5. Libtayo. Available at: <https://www.libtayohcp.com/>. Accessed December 26, 2023.