LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

EVIDENCE THAT EMPOWERS

- Proven first-line treatment in advanced NSCLC with no EGFR, ALK, or ROS1 aberrations[1]
- Approved for use in combination with chemo with any PD-L1 level or as a single agent when PD-L1 ≥50%[1]
- Trials included patients with both squamous and nonsquamous advanced NSCLC[1]

LIBTAYO combination therapy (EMPOWER-Lung 3)

NOW APPROVED

LIBTAYO in combination with platinum-based chemotherapy[1]

LIBTAYO in combination with platinum-based chemotherapy is indicated 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.[1]

LIBTAYO single agent (EMPOWER-Lung 1)

APPROVED IN 2021

LIBTAYO as a single agent[1]

LIBTAYO as a single agent is indicated for the first-line treatment of adult 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.[1]

LIBTAYO in combination with chemotherapy and LIBTAYO as a single agent achieved a median OS of more than 21 months in 2 pivotal trials in advanced NSCLC[1]

MEDIAN OS

LIBTAYO + chemotherapy: 21.9 months (95% CI, 15.5-NE)
Chemotherapy: 13.0 months (95% CI, 11.9-16.1),
HR=0.71, *P*=0.0140[1]

Number of deaths: 42% of patients (132 out of 312 patients) with LIBTAYO + chemotherapy and 53% of patients (82 out of 154 patients) with chemotherapy alone[1]

MEDIAN OS (ITT)

LIBTAYO: 22.1 months (95% CI, 17.7-NE)
Chemotherapy: 14.3 months (95% CI, 11.7-19.2),
HR=0.68, *P*=0.0022[1]

Number of deaths (ITT): 30% of patients (108 out of 356 patients) with LIBTAYO and 40% of patients (141 out of 354 patients) with chemotherapy[1]

Chemo=platinum-based chemotherapy.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1/PD-L1–blocking antibodies.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ALK=anaplastic lymphoma kinase; CI=confidence interval; EGFR=epidermal growth factor receptor; FDA=Food and Drug Administration; HR=hazard ratio; ITT=intention-to-treat; NE=not evaluable; OS=overall survival; PD-L1=programmed death ligand 1; ROS1=ROS proto-oncogene 1, receptor tyrosine kinase.

Advanced
NSCLC

Proven efficacy and established safety profile in trials that included squamous and nonsquamous advanced NSCLC[1]

First-line treatment options: Help fight advanced NSCLC by harnessing the power of the immune system. LIBTAYO can be used in adults with no EGFR, ALK, or ROS1 aberrations in combination with chemotherapy with any PD-L1 level or as a single agent when PD-L1 ≥50%.[1]

Proven efficacy: Both the EMPOWER-Lung 3 and EMPOWER-Lung 1 trials met the primary endpoints.[1-3]

Established safety profile: Safety of LIBTAYO in advanced NSCLC was studied across 667 patients in 2 pivotal trials.[1]*

LIBTAYO is a widely covered treatment option with a lower monthly cost, per list price, than other PD-1 inhibitors.[4]†

*In the LIBTAYO + chemotherapy arm and in the LIBTAYO arm.[1]

†Based on AnalySource.com. Accessed September 14, 2022. Monthly cost is based on the estimated wholesale acquisition cost (WAC) per recommended dosing regimen over a 28-day course of treatment. Analysis includes PD-1 inhibitors only and does not include PD-L1 agents. The dosing and indications of PD-1's differ and any pricing comparison is not intended to imply a clinical comparison.[4]

WAC is the manufacturer's undiscounted list price for a drug to wholesalers as reported to third-party drug-pricing publishers. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions in price. Most patients do not pay WAC. The amount patients pay for LIBTAYO will vary and largely depends on whether they have insurance, the type of insurance they have, whether their insurance provider considers the medication to be preferred or not preferred, and whether they have met their deductible.[4]

Warnings and Precautions for LIBTAYO[1]

Warnings and Precautions for LIBTAYO include severe and fatal immune-mediated adverse reactions such as immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and other immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic HSCT; and embryo-fetal toxicity. Monitor for symptoms and signs of immune-mediated adverse reactions.

For more information on Warnings and Precautions, please see additional Important Safety Information throughout and in Section 5 of the full Prescribing Information.

HSCT=hematopoietic stem cell transplantation; PD-1=programmed death receptor-1; WAC=wholesale acquisition cost.

LIBTAYO + chemo demonstrated powerful efficacy vs chemo alone[1]

Combination therapy: EMPOWER-Lung 3[1,2]

(LIBTAYO + platinum-based chemotherapy vs platinum-based chemotherapy; N=466)[1]*

Patients with advanced NSCLC and no EGFR, ALK, or ROS1 aberrations[1]

SUPERIOR OS

MEDIAN OS
21.9 MONTHS[1]

(95% CI, 15.5-NE) vs **13.0 months** (95% CI, 11.9-16.1) **with chemotherapy**, HR=0.71, *P*=0.0140[1]

Number of deaths: 42% of patients (132 out of 312 patients) with LIBTAYO + chemotherapy and 53% of patients (82 out of 154 patients) with chemotherapy alone[1]

DURATION OF RESPONSE[1,5†]

MEDIAN DOR
15.6 MONTHS[1]

(range, 1.7-18.7+ months) vs **7.3 months** (range, 1.8-18.8+ months) **with chemotherapy**[1]

ORR[1,2†]: 43% (95% CI, 38%-49%) vs **23%** (95% CI, 16%-30%) **with chemotherapy**, *P*<0.0001[1]

SAFETY DATA

- Serious adverse reactions occurred in 25% of patients who received LIBTAYO + chemotherapy. The most frequent serious adverse reactions that occurred in at least 2% of patients were pneumonia, anemia, and neutropenia[1]
- Fatal adverse reactions occurred in 6% of patients who received LIBTAYO + chemotherapy [including death not otherwise specified (2.9%), sudden death (1.0%), acute hepatitis (0.3%), acute respiratory distress syndrome (0.3%), mesenteric artery thrombosis (0.3%), pneumonia (0.3%), pneumonitis (0.3%), and pulmonary hemorrhage (0.3%)] vs 7.8% with chemotherapy alone[1,2]
- LIBTAYO + chemotherapy was permanently discontinued due to adverse reactions in 5% of patients vs 2.6% with chemotherapy alone[1,2]
- Dosage interruptions of LIBTAYO + chemotherapy due to adverse reactions occurred in 33% of patients[1]
- The most common adverse reactions (≥15%) in patients who received LIBTAYO + chemotherapy were alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite[1]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

In EMPOWER-Lung 3, OS was monitored and reviewed per IDMC. All secondary analyses were conducted per BICR.[1,2]

*Platinum-based chemotherapy in either arm consisted of carboplatin AUC of 5 or 6 mg/mL/min IV and paclitaxel 200 mg/m^2 IV; cisplatin 75 mg/m^2 IV and paclitaxel 200 mg/m^2 IV; carboplatin AUC of 5 or 6 mg/mL/min IV and pemetrexed 500 mg/m^2 IV; or cisplatin 75 mg/m^2 IV and pemetrexed 500 mg/m^2 IV. Maintenance pemetrexed was mandatory for patients with nonsquamous NSCLC who received a pemetrexed-containing chemotherapy regimen in the first 4 treatment cycles.[1]

†Secondary endpoint.[1,2,5]

+: Ongoing response.[1]

AUC=area under the curve; BICR=blinded independent central review; DOR=duration of response; IDMC=independent data monitoring committee; IV=intravenous; ORR=objective response rate.

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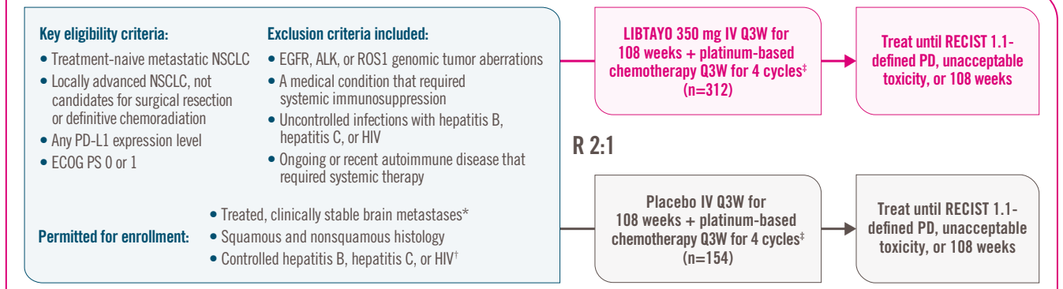
EMPOWER-Lung 3 was designed with broad inclusion criteria[1,2]

Enrolled patients with advanced NSCLC of any PD-L1 expression and both histologies[1,2]

Phase 3, randomized, multicenter, double-blind, active-controlled trial (N=466)[1,2,5]



Primary endpoint[1]:
- OS

Secondary endpoints included[1,2,5]:
- PFS (key), ORR (key), DOR, and safety and tolerability

Per IDMC recommendation:

Trial stopped early due to superior OS.[2]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

In EMPOWER-Lung 3, OS was monitored and reviewed per IDMC. All secondary analyses were conducted per BICR.[1,2]

*Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization.[1]

†No patients with HIV or hepatitis B were enrolled; only 2 patients with hepatitis C were enrolled.[4]

‡Platinum-based chemotherapy in either arm consisted of carboplatin AUC of 5 or 6 mg/mL/min IV and paclitaxel 200 mg/m^2 IV; cisplatin 75 mg/m^2 IV and paclitaxel 200 mg/m^2 IV; carboplatin AUC of 5 or 6 mg/mL/min IV and pemetrexed 500 mg/m^2 IV; or cisplatin 75 mg/m^2 IV and pemetrexed 500 mg/m^2 IV. Maintenance pemetrexed was mandatory for patients with nonsquamous NSCLC who received a pemetrexed-containing chemotherapy regimen in the first 4 treatment cycles.[1]

Randomization was stratified by histology (nonsquamous vs squamous) and PD-L1 expression (<1% vs 1% to 49% vs ≥50%) according to the VENTANA PD-L1 (SP263) assay.[1]

Median duration of treatment exposure was 38.5 weeks (IQR, 20.7-63.9 weeks) for LIBTAYO + chemotherapy and 21.3 weeks (IQR, 12.0-38.4 weeks) for placebo + chemotherapy.[2]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

No dose reduction for LIBTAYO is recommended. In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids.

Withhold or permanently discontinue LIBTAYO depending on severity. In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.

ECOG=Eastern Cooperative Oncology Group; IQR=interquartile range; PD=progressive disease; PFS=progression-free survival; PS=performance status; Q3W=every 3 weeks; R=randomization; RECIST=Response Evaluation Criteria in Solid Tumors.

Patient characteristics in EMPOWER-Lung 3[2,6]

%, unless stated	ITT (N=466) LIBTAYO + chemotherapy (n=312)	ITT (N=466) Chemotherapy (n=154)
Median age (range), years	63 (25-82)	63 (34-84)
≥65 years	41	39
Male	86	80
Histology		
Squamous	43	44
Nonsquamous	57	57
PD-L1 expression		
≥50%	33	32
1% to 49%	37	40
<1%	30	29
ECOG PS		
0	16	12
1	83	87
Brain metastases*	8	5
Cancer stage at screening		
Locally advanced	14	16
Metastatic	86	84
Smoking history		
Current smoker	55	49
Past smoker	31	36
Never-smoker	14	16

Chemo=platinum-based chemotherapy.

*Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization.[1]

LIBTAYO + chemo was examined in a clinical study designed to closely resemble a patient population with varied disease presentations that physicians manage in everyday clinical practice[2]:

43% had squamous histology[1]

14% had locally advanced disease and were ineligible for surgical resection or definitive chemoradiation[1]

8% had treated, clinically stable brain metastases[1]*

16% had liver metastases[4]

83% had an ECOG PS of 1[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

The incidence and severity of immune-mediated adverse reactions were similar when LIBTAYO was administered as a single agent or in combination with chemotherapy.

Immune-mediated pneumonitis: LIBTAYO can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 4 (0.5%), Grade 3 (0.5%), and Grade 2 (2.1%). Pneumonitis led to permanent discontinuation in 1.4% of patients and withholding of LIBTAYO in 2.1% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 58% of the 26 patients. Of the 17 patients in whom LIBTAYO was withheld, 9 reinitiated after symptom improvement; of these, 3/9 (33%) had recurrence of pneumonitis. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

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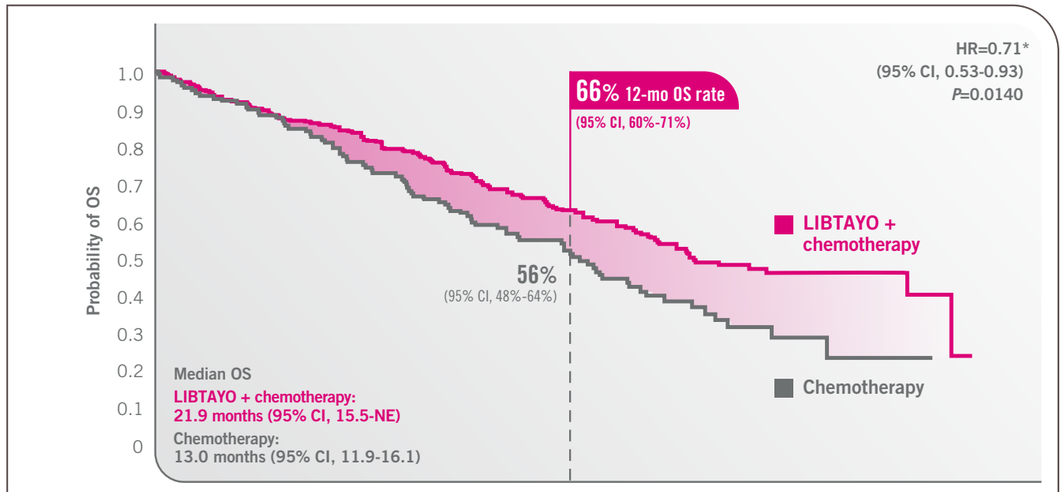
In patients with advanced NSCLC with no EGFR, ALK, or ROS1 aberrations[1]:

Significantly EXTENDED SURVIVAL: Median 21.9 months with LIBTAYO + chemo vs 13.0 months with chemo[1,2]



Number of subjects at risk

LIBTAYO + chemotherapy	312	289	269	256	233	199	162	131	86	52	18	8	0	0
Chemotherapy	154	141	126	112	98	85	65	46	26	14	5	2	0	0

29% REDUCTION IN RISK OF DEATH[1]

Number of deaths: 42% of patients (132 out of 312 patients) with LIBTAYO + chemotherapy and 53% of patients (82 out of 154 patients) with chemotherapy alone[1]

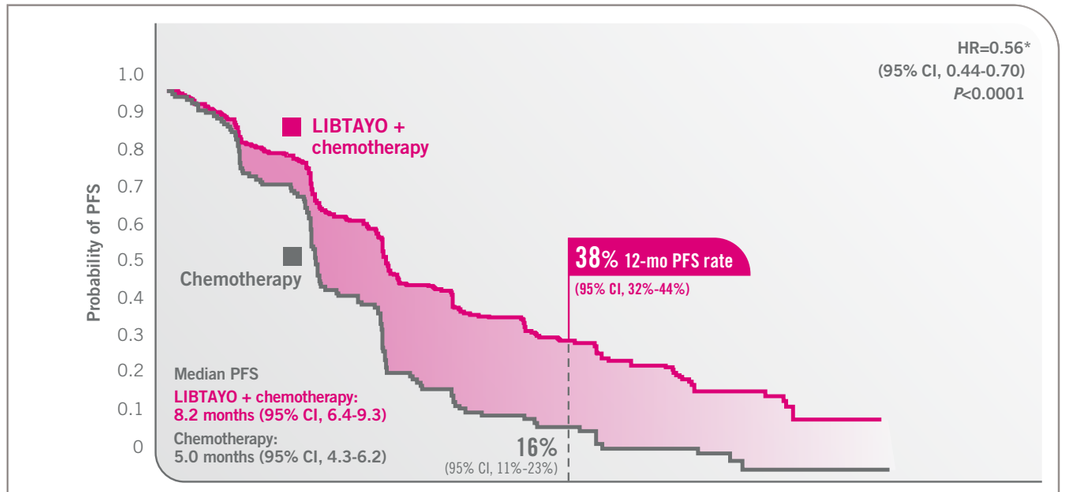
Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

*HR was based on stratified proportional hazards model.[1]

In patients with advanced NSCLC with no EGFR, ALK, or ROS1 aberrations[1]:

EXTENDED progression-free survival: Median 8.2 months with LIBTAYO + chemo vs 5.0 months with chemo[1,2]



Number of subjects at risk

LIBTAYO + chemotherapy	312	280	248	194	145	113	90	57	27	15	2	0	0	0
Chemotherapy	154	133	106	64	34	24	16	11	6	1	1	0	0	0

Adapted with permission from Gogishvili et al, *Nat Med*. 2022.[2]

44% REDUCTION IN RISK OF PROGRESSION[1]

Number of events: 65% of patients (204 out of 312 patients) with LIBTAYO + chemotherapy and 79% of patients (122 out of 154 patients) with chemotherapy alone[1]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

*HR was based on stratified proportional hazards model.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated colitis: LIBTAYO can cause immune-mediated colitis. The primary component of immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory immune-mediated colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2.2% (18/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (1.1%). Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBTAYO in 1.5% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated colitis (continued): Of the 12 patients in whom LIBTAYO was withheld, 4 reinitiated LIBTAYO after symptom improvement; of these, 3/4 (75%) had recurrence. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

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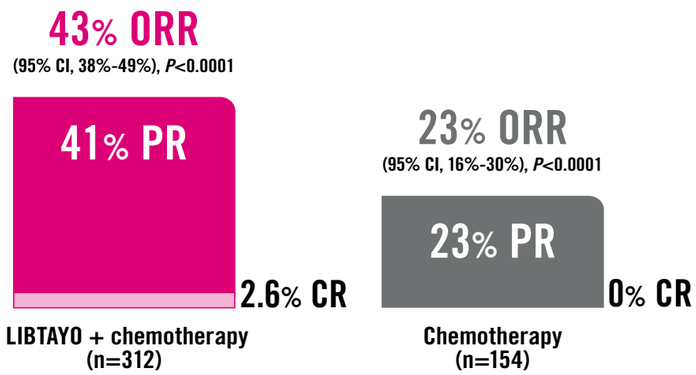
In patients with advanced NSCLC with no EGFR, ALK, or ROS1 aberrations[1]:

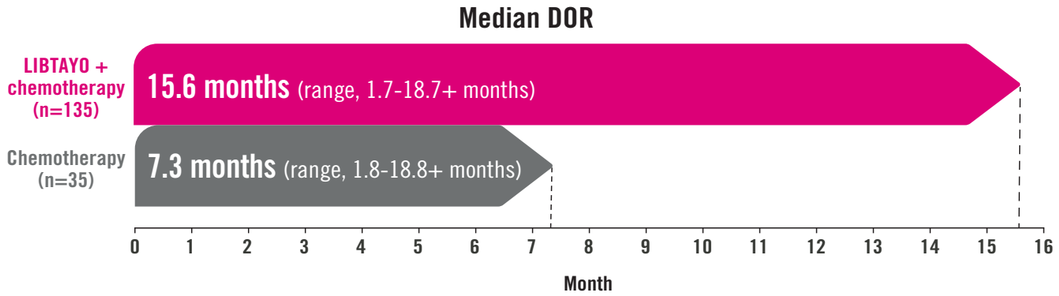
ORR was significantly HIGHER in patients treated with LIBTAYO + chemo vs chemo alone[1]

Objective response rate



Extended duration of response: Median 15.6 months with LIBTAYO + chemo vs 7.3 months with chemo alone[1]

Duration of response



Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

Based on patients with confirmed CR or PR.[1]

+: Ongoing response.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis: LIBTAYO can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2% (16/810) of patients receiving LIBTAYO, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (1.4%), and Grade 2 (0.2%). Hepatitis led to permanent discontinuation of LIBTAYO in 1.2% of patients and withholding of LIBTAYO in 0.5% of patients.

CR=complete response; PR=partial response.

In patients with advanced NSCLC with no EGFR, ALK, or ROS1 aberrations[1]:

Exploratory analyses of prespecified histology subgroups[2,4]

Limitations: These are exploratory analyses that were not powered to show statistically significant differences in histology. Firm conclusions cannot be made based on these exploratory analyses.[2]

Squamous	LIBTAYO + chemotherapy (n=133)	Chemotherapy (n=67)
Median OS, months (95% CI)	21.9 (15.6-NE)	13.8 (9.3-18.0)
HR (95% CI)*	0.56 (0.37-0.84)	
Median PFS, months (95% CI)	8.2 (6.3-10.4)	4.9 (4.1-6.2)
HR (95% CI)*	0.56 (0.40-0.79)	
ORR, %	47%	28%
OR (95% CI)†	2.21 (1.17-4.15)	
Median duration of follow-up (IQR), months	18.2 (15.9-20.2)	

Number of deaths: 43% of patients (57 out of 133 patients) with LIBTAYO + chemotherapy and 58% of patients (39 out of 67 patients) with chemotherapy alone[2]

Number of events: 74% of patients (98 out of 133 patients) with LIBTAYO + chemotherapy and 81% of patients (54 out of 67 patients) with chemotherapy alone[2]

Nonsquamous	LIBTAYO + chemotherapy (n=179)	Chemotherapy (n=87)
Median OS, months (95% CI)	15.8 (13.7-NE)	13.0 (10.0-NE)
HR (95% CI)*	0.79 (0.54-1.14)	
Median PFS, months (95% CI)	7.9 (6.3-10.4)	5.5 (4.3-6.2)
HR (95% CI)*	0.53 (0.39-0.73)	
ORR, %	41%	18%
OR (95% CI)†	3.06 (1.65-5.68)	
Median duration of follow-up (IQR), months	14.7 (12.5-17.9)	

Number of deaths: 42% of patients (75 out of 179 patients) with LIBTAYO + chemotherapy and 49% of patients (43 out of 87 patients) with chemotherapy alone[2]

Number of events: 59% of patients (106 out of 179 patients) with LIBTAYO + chemotherapy and 78% of patients (68 out of 87 patients) with chemotherapy alone[2]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Due to the capping applied to the enrollment of patients with squamous histology, median duration of follow-up was shorter in the nonsquamous subset vs the squamous subset.[2]

*HR <1 favors LIBTAYO.[2]

†OR >1 favors LIBTAYO.[2]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued): Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 19% (3/16) of these patients. Hepatitis resolved in 50% of the 16 patients. Of the 5 patients in whom LIBTAYO was withheld, 3 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

OR=odds ratio.

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LIBTAYO + chemo safety profile in EMPOWER-Lung 3[1]

Adverse reactions in ≥10% of patients[1]

Adverse reactions	LIBTAYO + chemotherapy (n=312)		Chemotherapy (n=153)	
	All grades, %	Grade 3 or 4, %	All grades, %	Grade 3 or 4, %
Skin and subcutaneous tissue disorders				
Alopecia	37	0	43	0
Rash*	13	1.3	6	0
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain†	30	1.6	36	0
Gastrointestinal disorders				
Nausea	25	0	16	0
Constipation	14	0.3	11	0
Vomiting	12	0	10	0
Diarrhea	11	1.3	7	0
General disorders and administration site conditions				
Fatigue‡	23	3.8	18	2
Nervous system disorders				
Peripheral neuropathy§	23	0	19	0
Metabolism and nutrition disorders				
Decreased appetite	17	1	12	0
Investigations				
Weight decreased	11	1.3	8	0
Respiratory, thoracic, and mediastinal disorders				
Dyspnea‖	13	2.2	7	0.7
Psychiatric disorders				
Insomnia	11	0	7	0

*Rash is a composite term that includes rash, rash maculopapular, dermatitis, psoriasis, rash papular, urticaria, dermatitis allergic, erythema, lichen planus, rash macular, rash pruritic, skin reaction, skin toxicity, skin exfoliation, and dermatitis acneiform.[1]

†Musculoskeletal pain is a composite term that includes arthralgia, back pain, pain in extremity, noncardiac chest pain, myalgia, bone pain, musculoskeletal pain, neck pain, musculoskeletal chest pain, arthritis, and spinal pain.[1]

‡Fatigue is a composite term that includes asthenia, fatigue, and malaise.[1]

§Peripheral neuropathy is a composite term that includes peripheral sensory neuropathy, peripheral neuropathy, paresthesia, polyneuropathy, hypoaesthesia, peripheral sensorimotor neuropathy, neuralgia, polyneuropathy in malignant disease, and toxic neuropathy.[1]

‖Dyspnea is a composite term that includes dyspnea and dyspnea exertional.[1]

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03.[1]

- **Serious adverse reactions occurred in 25% of patients** who received LIBTAYO + chemotherapy. The most frequent serious adverse reactions that occurred in **at least 2% of patients were pneumonia, anemia, and neutropenia**[1]
- **Fatal adverse reactions occurred in 6% of patients** who received LIBTAYO + chemotherapy [including death not otherwise specified (2.9%), sudden death (1.0%), acute hepatitis (0.3%), acute respiratory distress syndrome (0.3%), mesenteric artery thrombosis (0.3%), pneumonia (0.3%), pneumonitis (0.3%), and pulmonary hemorrhage (0.3%)] vs 7.8% with chemotherapy alone[1,2]
- Adverse reactions resulting in permanent discontinuation in **at least 2 patients** who received LIBTAYO + chemotherapy **were increased alanine aminotransferase and anemia**[1]
- **Dosage interruptions** of LIBTAYO + chemotherapy due to adverse reactions **occurred in 33% of patients.** Adverse reactions that required dosage interruptions in **at least 2% of patients were anemia, pneumonia, neutropenia, thrombocytopenia, fatigue, COVID-19 infection, and pyrexia**[1]
- The most common adverse reactions (≥15%) in patients who received LIBTAYO + chemotherapy **were alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite**[1]

Permanent discontinuation rates due to adverse reactions[1,2]:

5%
LIBTAYO + chemotherapy

2.6%
Chemotherapy alone

Chemo=platinum-based chemotherapy.

LIBTAYO + chemo safety profile in EMPOWER-Lung 3[1]

Grade 3 or 4 laboratory abnormalities worsening from baseline in ≥1% of patients[1]

Laboratory abnormalities	LIBTAYO + chemotherapy	Chemotherapy
	Grade 3 or 4, %*	
Chemistry		
Hyperglycemia	4	1.5
Increased alanine aminotransferase	3	2.1
Increased creatinine	2	1.4
Hypoalbuminemia	1	0
Hematology		
Anemia	10	7
Neutrophil count decreased	10	8
Lymphocyte count decreased	7	8
White blood cell decreased	6	4.1
Platelet count decreased	4.7	0.7
Electrolytes		
Hyponatremia	6	4.1
Hypophosphatemia	3.4	7
Hypocalcemia	3	2.1
Hyperkalemia	2.7	2.7
Hypermagnesemia	2.4	2.8
Hypokalemia	2.3	1.4
Hypercalcemia	1.7	0.7
Hypernatremia	1	0

- The most common Grade 3 or 4 laboratory abnormalities (≥2%) in patients who received LIBTAYO + chemotherapy **were anemia, neutropenia, lymphopenia, leukopenia, hyponatremia, thrombocytopenia, hyperglycemia, hypophosphatemia, increased alanine aminotransferase, hypocalcemia, hyperkalemia, hypermagnesemia, hypokalemia, and increased creatinine**[1]

Chemo=platinum-based chemotherapy.

*The denominator used to calculate the rate varied from 134 to 299 based on the number of patients with a baseline value and at least 1 posttreatment value.[1]

Toxicity was graded per NCI CTCAE v4.03.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued):

For hepatitis with no tumor involvement of the liver: Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 8 times the upper limit of normal (ULN) or if total bilirubin increases to more than 1.5 and up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 8 times the ULN or total bilirubin increases to more than 3 times the ULN.

For hepatitis with tumor involvement of the liver: Withhold LIBTAYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBTAYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO demonstrated powerful efficacy vs chemo[1]

Single agent: EMPOWER-Lung 1[1,3]

(LIBTAYO as a single agent vs platinum-based chemotherapy: ITT; N=710)[1]*

Patients with advanced NSCLC who had PD-L1 ≥50% and no EGFR, ALK, or ROS1 aberrations[1]

SUPERIOR OS

MEDIAN OS (ITT)
22.1 MONTHS[1]

(95% CI, 17.7-NE) vs **14.3 months** (95% CI, 11.7-19.2) **with chemotherapy**, HR=0.68, *P*=0.0022[1]

Number of deaths (ITT): 30% of patients (108 out of 356 patients) with LIBTAYO and 40% of patients (141 out of 354 patients) with chemotherapy[1]

DURATION OF RESPONSE[1,3†]

MEDIAN DOR (ITT)
21.0 MONTHS[1]

(range, 1.9+-23.3+ months) vs **6.0 months**
(range, 1.3+-16.5+ months) **with chemotherapy**[1]

ORR[1,3†]: 37% (95% CI, 32%-42%) vs **21%** (95% CI, 17%-25%) **with chemotherapy**[1]

SAFETY DATA

- Serious adverse reactions occurred in 28% of patients who received LIBTAYO[1]
- The most frequent serious adverse reactions in at least 2% of patients who received LIBTAYO were pneumonia and pneumonitis[1]
- 6% of patients permanently discontinued LIBTAYO due to adverse reactions vs 4% with chemotherapy alone[1,3]

PD-L1–positive (≥50%) advanced NSCLC[7]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[7]
CATEGORY 1‡ and preferred[7]

Negative for actionable molecular markers and no contraindications to PD-1 or PD-L1 inhibitors[7]

- **Cemiplimab-rwlc (LIBTAYO) is 1 out of 3 PD-1/PD-L1 inhibitors recommended in the NCCN Guidelines® as a Category 1‡ and preferred first-line monotherapy treatment for advanced or metastatic NSCLC[7§]**

NCCN Guidelines for Non-Small Cell Lung Cancer.

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

In EMPOWER-Lung 1, OS was monitored and reviewed per IDMC; PFS and all secondary analyses were conducted per BICR.[1,3,8]

*Investigator's choice: Paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology.[1,3,8]

†Secondary endpoint.[1,3]

‡**Category 1 recommendation is based upon high-level evidence and uniform NCCN consensus that the intervention is appropriate.[7]**

§See the NCCN Guidelines for detailed recommendations, including other preferred options.[7]

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

+: Ongoing response.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued):

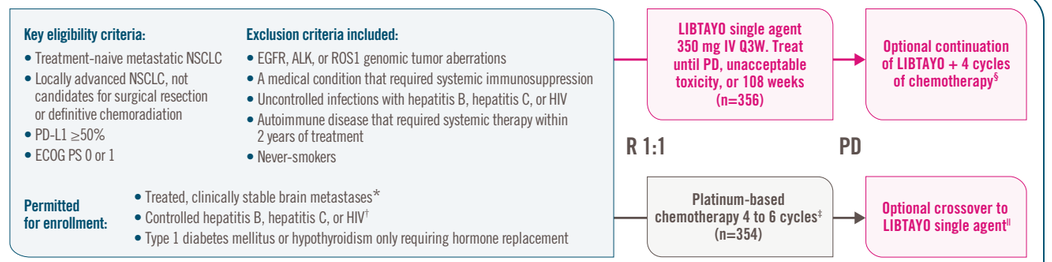
For hepatitis with tumor involvement of the liver (continued): Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times ULN or if total bilirubin increases to more than 3 times ULN. If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue LIBTAYO based on recommendations for hepatitis with no liver involvement.

NCCN=National Comprehensive Cancer Network.

In patients who had no EGFR, ALK, or ROS1 aberrations:

EMPOWER-Lung 1 was designed to enroll patients with advanced NSCLC who had PD-L1 ≥50%[1]

Phase 3, large, randomized, multicenter, open-label, active-controlled trial (ITT population; N=710)[1,3,8]



Primary endpoints[1]:
- OS and PFS

Secondary endpoints included[1,3]:
- ORR (key), DOR, and safety and tolerability

Per IDMC recommendation:
Trial stopped early due to superior OS.[3]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

The EMPOWER-Lung 1 study was designed to enroll patients with PD-L1 ≥50%.[3]

- A total of 710 patients were enrolled and randomized. For some patients, it was later determined that PD-L1 biomarker testing was not conducted according to the instructions for use, and required retesting[3]
- An analysis was conducted in a subset of patients with known PD-L1 ≥50% (n=563). The analysis excluded 91 patients from the overall population whose PD-L1 status was unknown because their tumors could not be retested, and 56 patients from the overall population who had <50% PD-L1 expression[3] (LIBTAYO is not indicated in patients with <50% PD-L1 expression.[1])

In EMPOWER-Lung 1, OS was monitored and reviewed per IDMC; PFS and all secondary analyses were conducted per BICR.[1,3,8]

*Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization.[1]

†Patients with HIV were allowed, but none were enrolled.[3,4]

‡Investigator's choice: Paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology.[1,3,8]

§Patients who experienced IRC-assessed RECIST 1.1-defined progressive disease on therapy with LIBTAYO were permitted to continue treatment with LIBTAYO 350 mg Q3W for up to 108 additional weeks, along with the addition of histology-specific chemotherapy for 4 cycles until further disease progression was observed.[1]

‖Patients who experienced IRC-assessed RECIST 1.1-defined progressive disease on chemotherapy were permitted to receive treatment with LIBTAYO for up to 108 weeks.[1,8]

Randomization was stratified by histology (nonsquamous vs squamous) and geographic region (Europe vs Asia vs rest of world).[1]

Median duration of exposure was 27.3 weeks (range, 9 days-115 weeks) for LIBTAYO vs 17.7 weeks (range, 18 days-86.7 weeks) for chemotherapy.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued): Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

IRC=independent review committee.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Patient characteristics in EMPOWER-Lung 1[3,4]

%, unless stated	ITT (N=710)	
	LIBTAYO (n=356)	Chemotherapy (n=354)
Median age (range), years	63 (31-79)	64 (40-84)
≥65 years	44	46
Male	88	83
Race or ethnicity		
White	87	86
Black or African American	0.3	1
Asian	11	11
Hispanic or Latino	10	7
Brain metastases*	12	11
ECOG PS		
0	27	27
1	73	73
Histology		
Squamous	45	43
Nonsquamous	55	57
Cancer stage at screening		
Locally advanced	18	15
Metastatic	82	85
Prior systemic therapy		
Neoadjuvant	1	2
Adjuvant	3	4

- In the subset of patients with known PD-L1 ≥50% (n=563), baseline patient and disease characteristics were consistent with those in the ITT population[3,4]

*Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization.[1]

LIBTAYO as a single agent was examined in a clinical study designed to closely resemble a patient population with varied disease presentations that physicians manage in everyday clinical practice[2,3]:

12%
had treated, clinically stable brain metastases[3]*

15%
had liver metastases[4]

2%
had controlled hepatitis B or hepatitis C[4]

18%
had locally advanced disease and were ineligible for surgical resection or definitive chemoradiation[3]

Important Safety Information (continued)

Warnings and Precautions (continued)

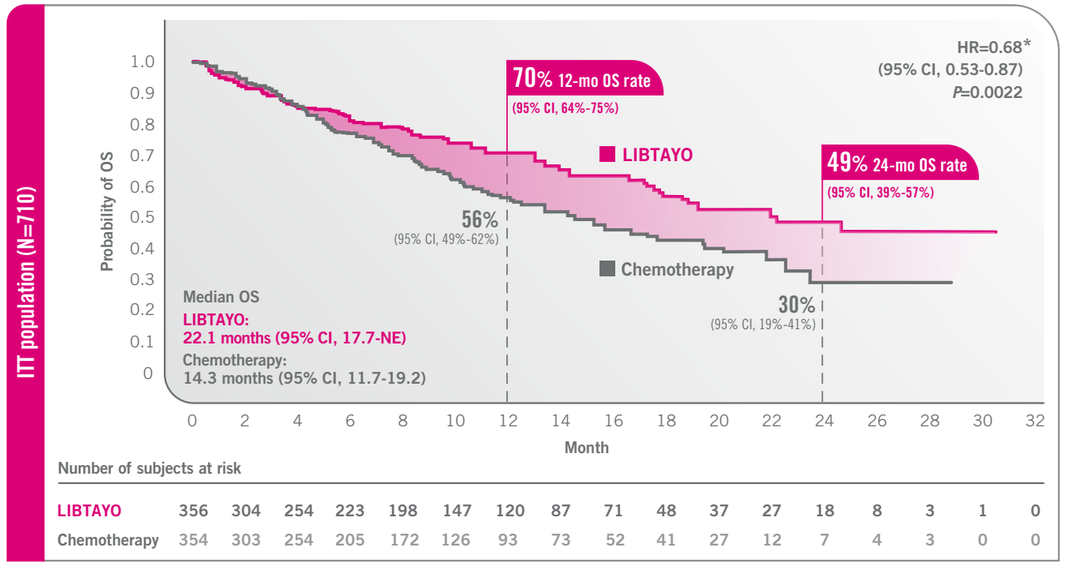
Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies: For Grade 3 or 4 endocrinopathies, withhold until clinically stable or permanently discontinue depending on severity.

- **Adrenal insufficiency:** LIBTAYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBTAYO depending on severity. Adrenal insufficiency occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.4%). Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. LIBTAYO was not withheld in any patient due to adrenal insufficiency. Systemic corticosteroids were required in all patients with adrenal insufficiency; of these, 67% (2/3) remained on systemic corticosteroids. Adrenal insufficiency had not resolved in any patient at the time of data cutoff
- **Hypophysitis:** LIBTAYO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue depending on severity. Hypophysitis occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient and withholding of LIBTAYO in 1 (0.1%) patient. Systemic corticosteroids were required in 67% (2/3) of patients with hypophysitis. Hypophysitis had not resolved in any patient at the time of data cutoff

Approved in patients with advanced NSCLC with PD-L1 ≥50% and no EGFR, ALK, or ROS1 aberrations[1]:

Significantly EXTENDED SURVIVAL: Median 22.1 months with LIBTAYO vs 14.3 months with chemo[1,8]



32% REDUCTION IN RISK OF DEATH[1]

Number of deaths: 30% of patients (108 out of 356 patients) with LIBTAYO and 40% of patients (141 out of 354 patients) with chemotherapy[1]

Nearly 3 out of 4 patients (74%) who progressed on platinum-based chemotherapy crossed over to LIBTAYO treatment[1]

Median PFS:

6.2 months (95% CI, 4.5-8.3) **with LIBTAYO vs 5.6 months** (95% CI, 4.5-6.1) **with chemotherapy**[1]

Number of events: 57% of patients (201 out of 356 patients) with LIBTAYO and 74% of patients (262 out of 354 patients) with chemotherapy[1]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

*HR was based on stratified proportional hazards model.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Thyroid disorders:** LIBTAYO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LIBTAYO depending on severity

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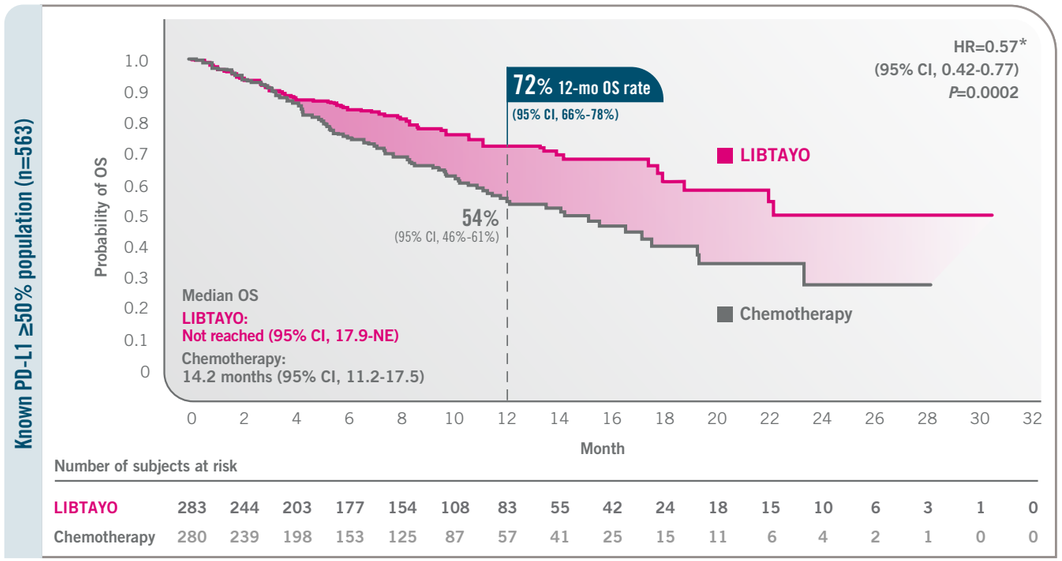
Injection 350 mg

In an analysis of the subset of patients with advanced NSCLC who had no EGFR, ALK, or ROS1 aberrations and known PD-L1 ≥50% (n=563):

Overall survival with LIBTAYO vs chemo in EMPOWER-Lung 1[3,8,9]



Adapted with permission from Sezer et al, *Lancet*. 2021.[3]

43% REDUCTION IN RISK OF DEATH[3,9]

Number of deaths: 25% of patients (70 out of 283 patients) with LIBTAYO and 38% of patients (105 out of 280 patients) with chemotherapy[3,9]

72% of patients who progressed on platinum-based chemotherapy crossed over to LIBTAYO treatment[4]

Median PFS:

8.2 months (95% CI, 6.1-8.8) **with LIBTAYO vs 5.7 months** (95% CI, 4.5-6.2) **with chemotherapy**[3,9]

Number of events: 52% of patients (147 out of 283 patients) with LIBTAYO and 70% of patients (197 out of 280 patients) with chemotherapy[3,9]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

*HR was based on stratified proportional hazards model.[3,9]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

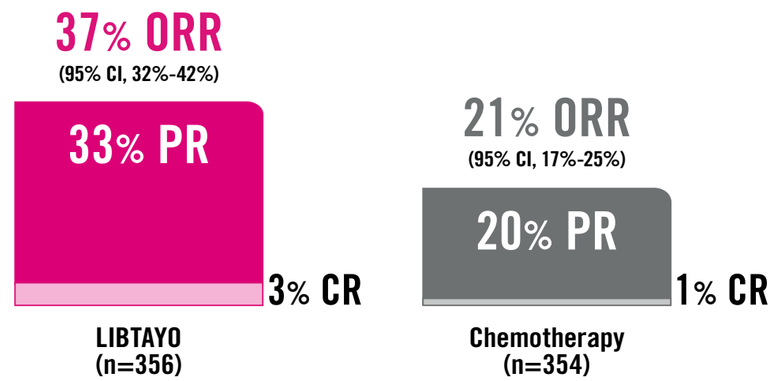
- **Thyroiditis:** Thyroiditis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including Grade 2 (0.2%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis had not resolved in any patient at the time of data cutoff. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported

Approved in patients with advanced NSCLC with PD-L1 ≥50% and no EGFR, ALK, or ROS1 aberrations[1]:

ORR was higher in patients treated with LIBTAYO vs chemo[1]

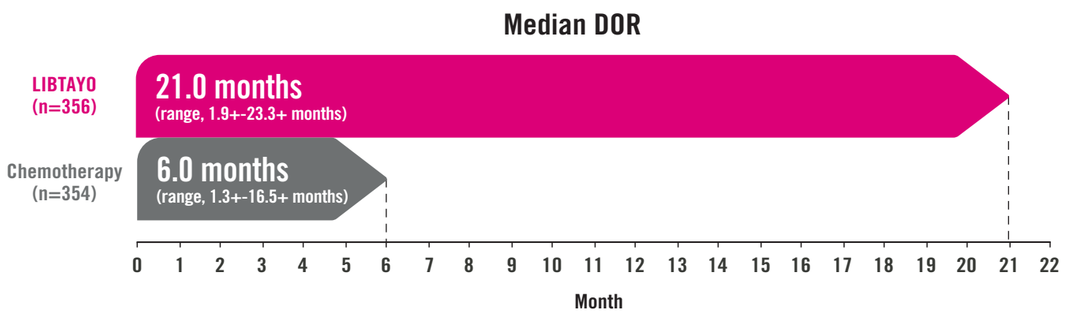
ITT population

Objective response rate*



Extended duration of response: Median 21.0 months with LIBTAYO vs 6.0 months with chemo[1,3]

Duration of response



Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

*Clopper-Pearson exact confidence interval.[1]

+: Ongoing response.[1]

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc)
Injection 350 mg

LIBTAYO safety profile in EMPOWER-Lung 1[1]

Adverse reactions in ≥10% of patients[1]

Adverse reactions	LIBTAYO (n=355)		Chemotherapy (n=342)	
	All grades, %	Grade 3 or 4, %	All grades, %	Grade 3 or 4, %
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain*	26	0.6	27	1.5
Skin and subcutaneous tissue disorders				
Rash†	15	1.4	6	0
Blood and lymphatic system disorders				
Anemia	15	3.4	50	16
General disorders and administration site conditions				
Fatigue‡	14	1.1	26	2
Metabolism and nutrition disorders				
Decreased appetite	12	0.6	18	0.3
Infections and infestations				
Pneumonia§	11	5	12	5
Respiratory, thoracic, and mediastinal disorders				
Cough‖	11	0	8	0.3

*Musculoskeletal pain is a composite term that includes back pain, arthralgia, pain in extremity, musculoskeletal pain, musculoskeletal chest pain, bone pain, myalgia, neck pain, spinal pain, and musculoskeletal stiffness.[1]

†Rash is a composite term that includes rash, dermatitis, urticaria, rash maculopapular, erythema, rash erythematous, rash pruritic, psoriasis, autoimmune dermatitis, dermatitis acneiform, dermatitis allergic, dermatitis atopic, dermatitis bullous, drug eruption, dyshidrotic eczema, lichen planus, and skin reaction.[1]

‡Fatigue is a composite term that includes fatigue, asthenia, and malaise.[1]

§Pneumonia is a composite term that includes atypical pneumonia, embolic pneumonia, lower respiratory tract infection, lung abscess, paracancerous pneumonia, pneumonia, pneumonia bacterial, and pneumonia klebsiella.[1]

‖Cough is a composite term that includes cough and productive cough.[1]

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03.[1]

- **Serious adverse reactions occurred in 28% of patients** who received LIBTAYO[1]
- The most frequent serious adverse reactions in **at least 2% of patients** who received LIBTAYO **were pneumonia and pneumonitis**[1]
- Adverse reactions resulting in permanent discontinuation in **at least 2 patients** who received LIBTAYO **were pneumonitis, pneumonia, ischemic stroke, and increased aspartate aminotransferase**[1]

Permanent discontinuation rates due to adverse reactions[1,3]:

6% LIBTAYO

4% Chemotherapy alone

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 0.5% of patients due to hyperthyroidism. Systemic corticosteroids were required in 3.8% (1/26) of patients. Hyperthyroidism resolved in 50% of 26 patients. Of the 4 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism
- **Hypothyroidism:** Hypothyroidism occurred in 7% (60/810) of patients receiving LIBTAYO, including Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. Hypothyroidism led to withholding of LIBTAYO in 1.1% of patients. Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 8.3% of the 60 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement; 1 required ongoing hormone replacement therapy
- **Type 1 diabetes mellitus, which can present with diabetic ketoacidosis:** Monitor for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBTAYO depending on severity. Type 1 diabetes mellitus occurred in 0.1% (1/810) of patients, including Grade 4 (0.1%). No patient discontinued treatment due to type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients

LIBTAYO safety profile in EMPOWER-Lung 1[1]

Grade 3 or 4 laboratory abnormalities worsening from baseline in ≥1% of patients[1]

Laboratory abnormalities	LIBTAYO (n=355)	Chemotherapy (n=342)
	Grade 3 or 4, %*	
Chemistry		
Increased aspartate aminotransferase	3.9	1.2
Increased alanine aminotransferase	2.7	0.3
Increased alkaline phosphatase	2.4	0.3
Increased blood bilirubin	2.1	0.3
Hypoalbuminemia	1.8	1.3
Increased creatinine	1.2	1.6
Hematology		
Lymphopenia	7	9
Anemia	2.7	16
Electrolytes		
Hyponatremia	6	7
Hyperkalemia	4.2	1.9
Hypocalcemia	3.9	3.4
Hypophosphatemia	2.4	4.1
Hypermagnesemia	2.1	1.6
Hypokalemia	1.5	2.2
Hypercalcemia	1.2	2.2

*Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter.[1]
Toxicity was graded per NCI CTCAE v4.03.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated nephritis with renal dysfunction: LIBTAYO can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including fatal (0.1%), Grade 3 (0.1%), and Grade 2 (0.4%). Nephritis led to permanent discontinuation in 0.1% of patients and withholding of LIBTAYO in 0.4% of patients. Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in 80% of the 5 patients. Of the 3 patients in whom LIBTAYO was withheld, 2 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence. Withhold LIBTAYO for Grade 2 or 3 increased blood creatinine, and permanently discontinue for Grade 4 increased blood creatinine. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immune-mediated dermatologic adverse reactions: LIBTAYO can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) has occurred with PD-1/PD-L1–blocking antibodies. Immune-mediated dermatologic adverse reactions occurred in 1.6% (13/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (0.6%).

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc)
Injection 350 mg

Immune-mediated adverse reactions on therapy with LIBTAYO[1]*

The safety of LIBTAYO was evaluated in 810 patients with advanced solid malignancies[1]

Immune-mediated adverse reactions	Adverse reactions, % (N=810)					Led to permanent treatment discontinuation, %	Led to treatment withholding, %	Required systemic corticosteroids, %	Adverse reactions resolved, %
	All grades, %	Grade 2, %	Grade 3, %	Grade 4, %	Fatal, %				
Pneumonitis	3.2	2.1	0.5	0.5	NR	1.4	2.1	100	58
Colitis	2.2	1.1	0.9	NR	NR	0.4	1.5	100	39
Hepatitis	2	0.2	1.4	0.1	0.1	1.2	0.5	100†	50
Endocrinopathies									
Adrenal insufficiency	0.4	NR	0.4	NR	NR	0.1	0	100	0
Hypophysitis‡	0.4	0.1	0.2	NR	NR	0.1	0.1	67	0
Thyroiditis§	0.6	0.2	NR	NR	NR	0	0.1	0	0
Hyperthyroidism	3.2	0.9	NR	NR	NR	0	0.5	3.8	50
Hypothyroidism‖	7	6	NR	NR	NR	0.1	1.1	0	8.3
Type 1 diabetes mellitus¶	0.1	NR	NR	0.1	NR	0	0.1	NR	NR
Nephritis with renal dysfunction	0.6	0.4	0.1	NR	0.1	0.1	0.4	100	80
Dermatologic#	1.6	0.6	0.9	NR	NR	0.1	1.4	100	69
Other imARs**	<1% for each	NR	NR	NR	NR	NR	NR	NR	NR

The incidence and severity of immune-mediated adverse reactions were similar when LIBTAYO was administered in combination with chemotherapy or as a single agent.[1]

*Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated reactions.[1]
†3 patients required additional immunosuppression with mycophenolate.[1]
‡Can cause hypopituitarism.[1]
§Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported.[1]
‖Majority of patients required long-term thyroid hormone replacement.[1]
¶Can present with diabetic ketoacidosis.[1]
#Exfoliative dermatitis, including SJS, TEN, and DRESS, has occurred with PD-1/PD-L1–blocking antibodies.[1]
**Cardiac/vascular: Myocarditis, pericarditis, vasculitis.[1]
Nervous system: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.[1]
Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other imARs, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.[1]
Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis.[1]
Musculoskeletal and connective tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.[1]
Endocrine: Hypoparathyroidism.[1]
Hematologic/immune: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection.[1]
NR=Not reported in the USPI. Does not necessarily mean the value is 0 and may have occurred in a small percentage of patients.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated dermatologic adverse reactions (continued): Immune-mediated dermatologic adverse reactions led to permanent discontinuation in 0.1% of patients and withholding of LIBTAYO in 1.4% of patients. Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 69% of the 13 patients.

DRESS=drug rash with eosinophilia and systemic symptoms; imARs=immune-mediated adverse reactions; SJS=Stevens-Johnson syndrome; TEN=toxic epidermal necrolysis.

LIBTAYO has straightforward dosing[1]

A fixed 350 mg dose from a single-dose vial

30 mins

An IV infusion over 30 minutes

Q3W

Every 3 weeks

Treatment should be continued until disease progression or unacceptable toxicity.[1]

Administration:

Refer to the respective Prescribing Information for the chemotherapy agents administered in combination with LIBTAYO for additional recommended dosing information, as appropriate.[1]

LIBTAYO Surround® can help support patients throughout their treatment journey

LIBTAYO SURROUND®

Visit **LIBTAYOSurround.com** to learn more.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated dermatologic adverse reactions (continued): Of the 11 patients in whom LIBTAYO was withheld for dermatologic adverse reactions, 7 reinitiated LIBTAYO after symptom improvement; of these, 43% (3/7) had recurrence of the dermatologic adverse reaction. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold LIBTAYO for suspected SJS, TEN, or DRESS. Permanently discontinue LIBTAYO for confirmed SJS, TEN, or DRESS. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 810 patients who received LIBTAYO or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

- **Cardiac/vascular:** Myocarditis, pericarditis, and vasculitis. Permanently discontinue for Grades 2, 3, or 4 myocarditis
- **Nervous system:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy. Withhold for Grade 2 neurological toxicities and permanently discontinue for Grades 3 or 4 neurological toxicities. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis
- **Musculoskeletal and connective tissue:** Myositis/polymyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
- **Endocrine:** Hypoparathyroidism
- **Other (hematologic/immune):** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.1% of patients receiving LIBTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. The most common symptoms of infusion-related reaction were nausea, pyrexia, rash, and dyspnea. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Complications of allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse Reactions

LIBTAYO as a single agent: the most common adverse reactions (≥15%) are musculoskeletal pain, fatigue, rash, and diarrhea

LIBTAYO in combination with platinum-based chemotherapy: the most common adverse reactions (≥15%) are alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite

Use in Specific Populations

- **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

LIB.22.08.0063

Please see accompanying full Prescribing Information.

References

1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Gogishvili M, Melkadze T, Makharadze T, et al. Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: a randomized, controlled, double-blind phase 3 trial [published online ahead of print: August 25, 2022]. *Nat Med.* 2022. https://www.nature.com/articles/s41591-022-01977-y.pdf. Accessed September 27, 2022. **3.** Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. *Lancet.* 2021;397(10274):592-604. **4.** Data on file. Regeneron Pharmaceuticals, Inc. **5.** Gogishvili M, Melkadze T, Makharadze T, et al. Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: a randomized, controlled, double-blind phase 3 trial [published online ahead of print: August 25, 2022]. *Nat Med.* 2022. Supplementary information available at: https://static-content.springer.com/esm/art%3A10.1038%2Fs41591-022-01977-y/MediaObjects/41591_2022_1977_MOESM1_ESM.pdf. Accessed September 27, 2022. **6.** Gogishvili M, Melkadze T, Makharadze T, et al. EMPOWER-Lung 3: cemiplimab in combination with platinum-doublet chemotherapy (chemo) for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC). Paper presented at: European Society for Medical Oncology (ESMO) Virtual Congress 2021; 19 September 2021. **7.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.5.2022.* © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed September 27, 2022. To view the most recent and complete version of the guidelines, go online to NCCN.org. **8.** Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. *Lancet.* 2021;397(10274)(suppl):1-178. **9.** PD-L1 IHC 22C3 pharmDx [instructions for use]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2021.

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

In combination with chemo or as a single agent:

LIBTAYO is a powerful first-line treatment option for advanced NSCLC[1]

Combination therapy: EMPOWER-Lung 3[1,2]

(LIBTAYO + platinum-based chemotherapy vs platinum-based chemotherapy; N=466)[1]*

Patients with advanced NSCLC and no EGFR, ALK, or ROS1 aberrations[1]

SUPERIOR OS

MEDIAN OS

21.9 MONTHS[1]

(95% CI, 15.5-NE) vs **13.0 months** (95% CI, 11.9-16.1) **with chemotherapy**, HR=0.71, *P*=0.0140[1]

Number of deaths: 42% of patients (132 out of 312 patients) with LIBTAYO + chemotherapy and 53% of patients (82 out of 154 patients) with chemotherapy alone[1]

DURATION OF RESPONSE[1,5†]

MEDIAN DOR

15.6 MONTHS[1]

(range, 1.7-18.7+ months) vs **7.3 months** (range, 1.8-18.8+ months) **with chemotherapy**[1]

ORR[1,2†]: 43% (95% CI, 38%-49%) vs **23%** (95% CI, 16%-30%) **with chemotherapy**, *P*<0.0001[1]

SAFETY DATA

- Serious adverse reactions occurred in 25% of patients who received LIBTAYO + chemotherapy. The most frequent serious adverse reactions that occurred in at least 2% of patients were pneumonia, anemia, and neutropenia[1]
- Fatal adverse reactions occurred in 6% of patients who received LIBTAYO + chemotherapy [including death not otherwise specified (2.9%), sudden death (1.0%), acute hepatitis (0.3%), acute respiratory distress syndrome (0.3%), mesenteric artery thrombosis (0.3%), pneumonia (0.3%), pneumonitis (0.3%), and pulmonary hemorrhage (0.3%)] vs 7.8% with chemotherapy alone[1,2]
- LIBTAYO + chemotherapy was permanently discontinued due to adverse reactions in 5% of patients vs 2.6% with chemotherapy alone[1,2]
- Dosage interruptions of LIBTAYO + chemotherapy due to adverse reactions occurred in 33% of patients[1]
- The most common adverse reactions (≥15%) in patients who received LIBTAYO + chemotherapy were alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite[1]

Single agent: EMPOWER-Lung 1[1,3]

(LIBTAYO as a single agent vs platinum-based chemotherapy: ITT; N=710)[1‡]

Patients with advanced NSCLC who had PD-L1 ≥50% and no EGFR, ALK, or ROS1 aberrations[1]

SUPERIOR OS

MEDIAN OS (ITT)

22.1 MONTHS[1]

(95% CI, 17.7-NE) vs **14.3 months** (95% CI, 11.7-19.2) **with chemotherapy**, HR=0.68, *P*=0.0022[1]

Number of deaths (ITT): 30% of patients (108 out of 356 patients) with LIBTAYO and 40% of patients (141 out of 354 patients) with chemotherapy[1]

DURATION OF RESPONSE[1,3†]

MEDIAN DOR (ITT)

21.0 MONTHS[1]

(range, 1.9+-23.3+ months) vs **6.0 months** (range, 1.3+-16.5+ months) **with chemotherapy**[1]

ORR[1,3†]: 37% (95% CI, 32%-42%) vs **21%** (95% CI, 17%-25%) **with chemotherapy**[1]

SAFETY DATA

- Serious adverse reactions occurred in 28% of patients who received LIBTAYO[1]
- The most frequent serious adverse reactions in at least 2% of patients who received LIBTAYO were pneumonia and pneumonitis[1]
- 6% of patients permanently discontinued LIBTAYO due to adverse reactions vs 4% with chemotherapy alone[1,3]

Advanced NSCLC is locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.[1]

Chemo=platinum-based chemotherapy.

In EMPOWER-Lung 3, OS was monitored and reviewed per IDMC. All secondary analyses were conducted per BICR.[1,2]

In EMPOWER-Lung 1, OS was monitored and reviewed per IDMC; PFS and all secondary analyses were conducted per BICR.[1,3,8]

*Platinum-based chemotherapy in either arm consisted of carboplatin AUC of 5 or 6 mg/mL/min IV and paclitaxel 200 mg/m^2 IV; cisplatin 75 mg/m^2 IV and paclitaxel 200 mg/m^2 IV; carboplatin AUC of 5 or 6 mg/mL/min IV and pemetrexed 500 mg/m^2 IV; or cisplatin 75 mg/m^2 IV and pemetrexed 500 mg/m^2 IV. Maintenance pemetrexed was mandatory for patients with nonsquamous NSCLC who received a pemetrexed-containing chemotherapy regimen in the first 4 treatment cycles.[1]

†Secondary endpoint.[1,2,3,5]

‡Investigator's choice: Paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology.[1,3,8]

+: Ongoing response.[1]

Warnings and Precautions for LIBTAYO[1]

Warnings and Precautions for LIBTAYO include severe and fatal immune-mediated adverse reactions such as immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and other immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic HSCT; and embryo-fetal toxicity. Monitor for symptoms and signs of immune-mediated adverse reactions.

For more information on Warnings and Precautions, please see additional Important Safety Information throughout and in Section 5 of the full Prescribing Information.

REGENERON

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg