**CLINICAL INSIGHTS**

# Summary of the product theater presented at Perspectives in Lung Cancer Care: LIBTAYO® (cemiplimab-rwlc), an FDA-approved first-line monotherapy option in advanced non-small cell lung cancer (NSCLC)[1]

**August 5th, 2021**

***LIBTAYO® is APPROVED for the first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression (tumor proportion score ≥50%) as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is[1]:***

- ***locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or***
- ***metastatic***


Presented by:

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## NSCLC background

Lung cancer is the leading cause of cancer-related mortality, accounting for approximately 25% of all cancer deaths.[2] In 2021, over 235,000 adults will be diagnosed with lung cancer in the United States.[2] The most common form of lung cancer is NSCLC, which accounts for nearly 84% of all lung cancer diagnoses.[2] At diagnosis, an estimated 75% of patients with NSCLC will present with advanced NSCLC and have poor survival prognosis.[3] Patients with advanced NSCLC at diagnosis are not typically candidates for curative surgery[4,5] and are often treated with systemic therapy to help prolong survival.[6]

## 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. 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.

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


This supplement was sponsored by Regeneron and Sanofi Genzyme.
Mark Socinski, MD presented at the product theater, and was compensated for participation.

## Historical clinical trial eligibility considerations in advanced NSCLC

Certain patients with advanced NSCLC have historically been excluded from clinical trials because of failure to meet eligibility requirements to participate in such trials.[7-14] A number of organizations, such as the US Food and Drug Administration, the American Society of Clinical Oncology, and Friends of Cancer Research, have recognized the need to expand eligibility for oncology clinical trials and collaborated to identify specific eligibility criteria that are most likely to restrict participation and least likely to impact the safety of trial participants.[7,8,15-17] LUNGevity, a patient advocacy group, then applied these recommendations specifically to advanced lung cancer trials.[8] These organizations have recommended that, in appropriate cases, trials should consider inclusion of certain patients such as those with treated and stable brain metastases, chronic viral infections (including human immunodeficiency virus [HIV] and hepatitis B or C virus [HBV or HCV]), or history of prior or concurrent malignancies.[7,8,16,17] Thus, inclusion of potentially underrepresented populations in advanced NSCLC trials may help to provide insight that may be transferrable to clinical practice.

## LIBTAYO® (cemiplimab-rwlc) was studied in one of the largest clinical trials of patients with advanced NSCLC expressing PD-L1 ≥50%

The efficacy and safety of LIBTAYO were evaluated in a large, randomized, multicenter, open-label, active-controlled phase 3 trial.[1] The EMPOWER-Lung 1 study enrolled patients with[1,18]:

- Treatment-naive metastatic NSCLC or locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation
- Programmed death-ligand 1 (PD-L1) expression ≥50% of tumor cells
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

Patients were excluded from the trial if they had EGFR, ALK, or ROS1 genomic tumor aberrations, medical conditions that require systemic immunosuppression, uncontrolled infection with HBV, HCV, or HIV, autoimmune disease requiring systemic therapy within 2 years of treatment, or had never smoked.[1,18] Notably, patients with brain metastases were permitted to be enrolled if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization; radiological confirmation of stability or response was not required.[1,18] Additionally, patients were eligible to be enrolled if they presented with controlled HBV, HCV, or HIV, type 1 diabetes mellitus, or hypothyroidism only requiring hormone replacement.[18]

Patients enrolled were randomized (1:1) to receive LIBTAYO 350 mg intravenously every 3 weeks until disease progression, unacceptable toxicity or for up to 108 weeks, or investigator's choice of a platinum-doublet chemotherapy regimen for 4 to 6 cycles (**Figure 1**).[1] Patients who experienced independent review committee (IRC)-assessed, RECIST 1.1–defined progressive disease on LIBTAYO were permitted to continue treatment with LIBTAYO (up to an additional 108 weeks) with the addition of 4 cycles of histology-specific chemotherapy until further progression was observed.[1] Patients who experienced IRC-assessed, RECIST 1.1–defined progressive disease on chemotherapy were permitted to cross over to receive LIBTAYO for up to 108 weeks.[1,18] Tumor response assessments were performed every 9 weeks.[1] The primary efficacy endpoints were overall survival (OS) and progression-free survival (PFS).[1,18] Secondary endpoints included objective response rate (ORR), duration of response (DOR), safety, and tolerability.[18,19]

# Important Safety Information (cont'd)

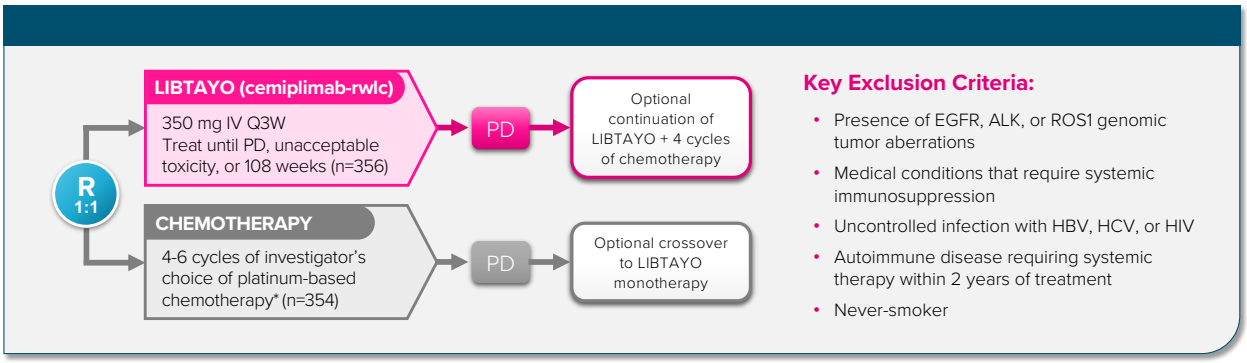
## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

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.

**Figure 1. EMPOWER-Lung 1 Study Design (N=710)[1]**




*Platinum-based chemotherapy regimens included any of the following: (1) paclitaxel + cisplatin or carboplatin, (2) gemcitabine + cisplatin or carboplatin, or (3) pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance for patients with non-squamous histology who received a pemetrexed containing regimen. ALK, anaplastic lymphoma kinase; EGFR, epidermal growth factor receptor; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IV, intravenous; PD, progressive disease; Q3W, every 3 weeks; R, randomized; ROS1, c-ros oncogene 1.

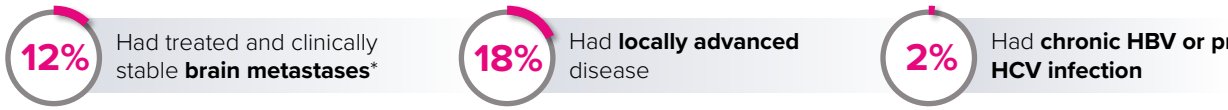
The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

The EMPOWER-Lung 1 study was designed to enroll patients with PD-L1 ≥50%, with PD-L1 expression determined using the PD-L1 IHC 22C3 pharmDx kit[18]:

- 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
- 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 (LIBTAYO is not indicated in patients with <50% PD-L1 expression)

In the intent-to-treat (ITT) population of 710 patients, median age was 63 years (range: 31-84 years), with 45% of patients aged 65 or older.[1] The majority of patients were male and White, with ECOG performance status of 1 and presenting with non-squamous histology.[1,18] In the subset of 563 patients with known PD-L1 ≥50%, baseline patient and disease characteristics were consistent with those in the ITT population.[18,20]

The study also included historically underrepresented populations; in the LIBTAYO arm (ITT population) at baseline[18,19]:




Patients with HIV were permitted to enroll, but none were recruited.[19]

*Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization. Radiological confirmation of stability or response was not required.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

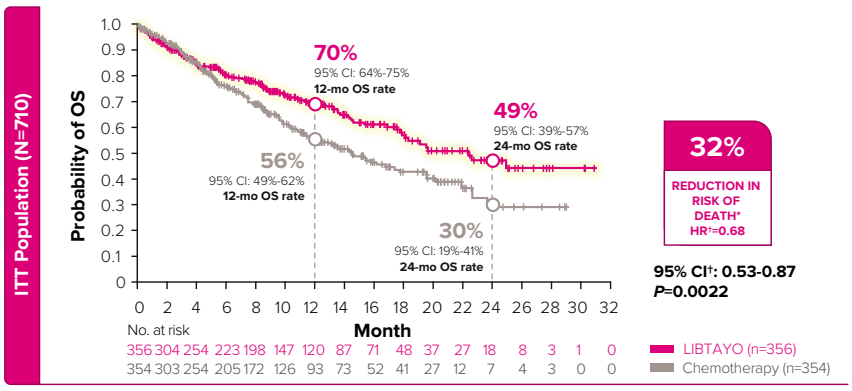
### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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.

## LIBTAYO® (cemiplimab-rwlc) demonstrated significant improvements in OS and PFS vs platinum-based chemotherapy in EMPOWER-Lung 1[1,18]

In the ITT population (N=710), the trial demonstrated a statistically significant improvement in OS and PFS for patients randomized to LIBTAYO compared with chemotherapy (**Figure 2** and **Table 1**).[1,18] Data for additional efficacy endpoints for the ITT population are shown in **Table 1**.

**Figure 2. LIBTAYO Significantly Extended Survival vs Platinum-Based Chemotherapy in EMPOWER-Lung 1 (ITT; N=710)[1,18]**




- Median OS‡ was 22.1 months (95% CI: 17.7 months-NE) with LIBTAYO vs 14.3 months (95% CI: 11.7-19.2) with chemotherapy[1]
- Deaths observed: 30% (108/356) with LIBTAYO and 40% (141/354) with chemotherapy[1]
- Of the patients randomized to receive chemotherapy who had disease progression, 74% crossed over to receive treatment with LIBTAYO[1]

*Median duration of follow-up was 13.1 months in both LIBTAYO and chemotherapy arms. †Based on stratified proportional hazards model. ‡Based on Kaplan-Meier method. HR, hazard ratio; ITT, intent-to-treat; NE, not evaluable; OS; overall survival.

**Table 1. Additional Efficacy Endpoints for the ITT Population (N=710)[1,18]**

| | ITT (N=710) | |
|---|---|---|
| | **LIBTAYO** (n=356) | Chemotherapy* (n=354) |
| **PFS per BICR** | | |
| **Median PFS**, months (95% CI)† | **6.2** (4.5-8.3) | **5.6** (4.5-6.1) |
| **HR** (95% CI)‡; *P* value | **0.59** (0.49-0.72); *P*<0.0001 | |
| **Number of events** (%) | **201** (57) | **262** (74) |
| **ORR§ per BICR** | | |
| **ORR**, % (95% CI) | **37** (32-42) | **21** (17-25) |
| **Complete response rate**, % | 3 | 1 |
| **Partial response rate**, % | 33 | 20 |
| **DOR per BICR** | | |
| **Median DOR**, months (range) | **21.0** (1.9+, 23.3+) | **6.0** (1.3+, 16.5+) |

*Platinum-based chemotherapy regimens included any of the following: (1) paclitaxel + cisplatin or carboplatin, (2) gemcitabine + cisplatin or carboplatin, or (3) pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance for patients with non-squamous histology. †Based on Kaplan-Meier method. ‡Based on stratified proportional hazards model. §Clopper-Pearson exact confidence interval. BICR, blinded independent central review; DOR, duration of response; HR, hazard ratio; ITT, intent-to-treat; ORR, objective response rate; PFS, progression-free survival; +, ongoing response.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

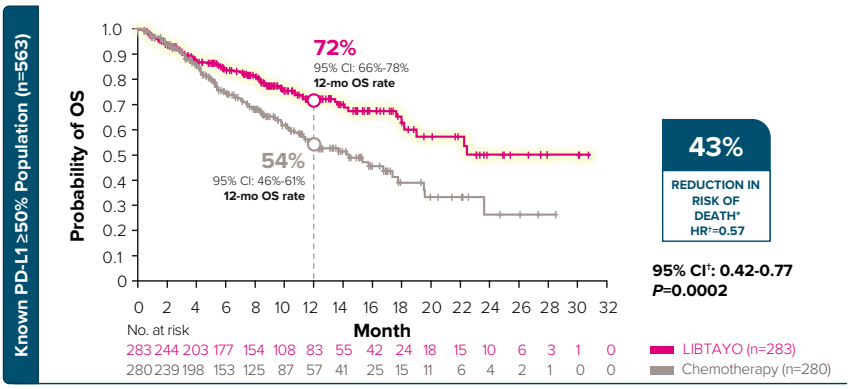
### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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.

## 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): OS with LIBTAYO® (cemiplimab-rwlc) vs platinum-based chemotherapy[18,20]

Data for OS and additional efficacy endpoints for the subset of 563 patients with known PD-L1 ≥50% are presented in **Figure 3** and **Table 2** below.

### Figure 3. OS with LIBTAYO vs Platinum-Based Chemotherapy in the Subset of Patients with Known PD-L1 ≥50% (n=563)[18,20]




- Median OS‡ was not reached (95% CI: 17.9 months-NE) with LIBTAYO vs 14.2 months (95% CI: 11.2-17.5) with chemotherapy[18,20]
- Deaths observed: 25% (70/283) with LIBTAYO and 38% (105/280) with chemotherapy[18,20]
- Of the patients randomized to receive chemotherapy who had disease progression, 72% crossed over to receive treatment with LIBTAYO[19]

*Median duration of follow-up was 10.8 months for LIBTAYO and 10.9 months for chemotherapy. †Based on stratified proportional hazards model. ‡Based on Kaplan-Meier method. HR, hazard ratio; NE, not evaluable; OS; overall survival.

### Table 2. Additional Efficacy Endpoints for the Subset of Patients with Known PD-L1 ≥50% (n=563)[18,20]

| | Known PD-L1 ≥50% (n=563) | |
|---|---|---|
| | **LIBTAYO** (n=283) | Chemotherapy* (n=280) |
| **PFS per BICR** | | |
| **Median PFS**, months (95% CI)† | **8.2** (6.1-8.8) | **5.7** (4.5-6.2) |
| **HR** (95% CI)‡; *P* value | **0.54** (0.43-0.68); *P*<0.0001 | |
| **Number of events** (%) | **147** (52) | **197** (70) |
| **ORR§,¶ per BICR** | | |
| **ORR**, % (95% CI) | **39** (34-45) | **20** (16-26) |
| **Complete response rate**, % | 2 | 1 |
| **Partial response rate**, % | 37 | 19 |
| **DOR¶ per BICR** | | |
| **Median DOR**, months (range) | **16.7** (1.9+, 23.3+) | **6.0** (1.3+, 14.5+) |

*Platinum-based chemotherapy regimens included any of the following: (1) paclitaxel + cisplatin or carboplatin, (2) gemcitabine + cisplatin or carboplatin, or (3) pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance for patients with non-squamous histology. †Based on Kaplan-Meier method. ‡Based on stratified proportional hazards model. §Clopper-Pearson exact confidence interval. ¶Not a prespecified endpoint in the subset of 563 patients with known PD-L1 ≥50%. BICR, blinded independent central review; DOR, duration of response; HR, hazard ratio; ORR, objective response rate; PFS, progression-free survival; +, ongoing response.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

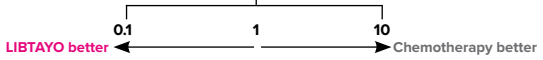
### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Immune-mediated colitis (cont'd):** Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients. 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.

## Subgroup analysis of OS in the ITT population[18]

**Figure 4. Subgroup Analysis of OS in the ITT Population (N=710)**

| ITT (N=710) | Events, n (total) | | HR (95% CI) |
|---|---|---|---|
| | LIBTAYO (cemiplimab-rwlc) | Chemotherapy | |
| **Overall** | **108 (356)** | **141 (354)** | **0.68 (0.53-0.87)** |
| **Age, years** | | | |
| <65 | 61 (200) | 71 (190) | 0.72 (0.51-1.02) |
| ≥65 | 47 (156) | 70 (164) | 0.63 (0.43-0.91) |
| **Sex** | | | |
| Male | 93 (312) | 123 (294) | 0.64 (0.49-0.84) |
| Female | 15 (44) | 18 (60) | 0.87 (0.42-1.78) |
| **Region of enrollment** | | | |
| Europe | 85 (275) | 119 (278) | 0.62 (0.47-0.82) |
| Asia | 10 (39) | 8 (38) | 1.34 (0.52-3.42) |
| Rest of the world | 13 (42) | 14 (38) | 0.73 (0.34-1.56) |
| **ECOG PS** | | | |
| 0 | 25 (96) | 32 (96) | 0.78 (0.46-1.32) |
| 1 | 83 (260) | 109 (258) | 0.66 (0.49-0.88) |
| **Histology*** | | | |
| Squamous | 45 (159) | 65 (152) | 0.53 (0.36-0.77) |
| Nonsquamous | 63 (197) | 76 (202) | 0.83 (0.59-1.16) |
| **Brain metastases at baseline*** | | | |
| Yes | 9 (44) | 15 (39) | 0.44 (0.19-1.07) |
| No | 99 (312) | 126 (315) | 0.71 (0.54-0.92) |
| **Cancer stage at screening*** | | | |
| Locally advanced | 17 (63) | 16 (52) | 0.85 (0.43-1.68) |
| Metastatic | 91 (293) | 125 (302) | 0.68 (0.52-0.89) |




**LIMITATIONS:** OS subgroup analyses were not powered to show a statistically significant difference between or within individual subgroups. Furthermore, histology, brain metastases at baseline, and cancer stage at screening were not prespecified subgroup analyses. Firm conclusions cannot be made based on these subgroup analyses.

Reprinted from *The Lancet,* Vol 397, Sezer A, 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. Pages 592-604, 2021, with permission from Elsevier. *These subgroup analyses were not prespecified. ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; ITT, intent-to-treat; OS, overall survival.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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. 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.

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.

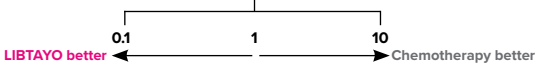
For hepatitis with tumor involvement of the liver: Withhold LIBTAYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBTAYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to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

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.

## In the subset of patients with advanced NSCLC who had no EGFR, ALK, or ROS1 aberrations and known PD-L1 ≥50% (n=563): Post hoc subgroup analysis of OS[18]

**Figure 5. Post Hoc Subgroup Analysis of OS in the Subset of Patients with Known PD-L1 ≥50% (n=563)***

| Known PD-L1 ≥50% (n=563) | Events, n (total) | | HR (95% CI) |
|---|---|---|---|
| | LIBTAYO (cemiplimab-rwlc) | Chemotherapy | |
| **Overall** | **70 (283)** | **105 (280)** | **0.57 (0.42-0.77)** |
| **Age, years** | | | |
| <65 | 41 (157) | 50 (147) | 0.66 (0.44-1.00) |
| ≥65 | 29 (126) | 55 (133) | 0.48 (0.30-0.76) |
| **Sex** | | | |
| Male | 58 (248) | 92 (231) | 0.50 (0.36-0.69) |
| Female | 12 (35) | 13 (49) | 1.11 (0.49-2.52) |
| **Region of enrollment** | | | |
| Europe | 55 (215) | 84 (216) | 0.54 (0.39-0.77) |
| Asia | 5 (31) | 7 (29) | 0.76 (0.24-2.41) |
| Rest of the world | 10 (37) | 14 (35) | 0.59 (0.26-1.33) |
| **ECOG PS** | | | |
| 0 | 18 (77) | 23 (75) | 0.77 (0.41-1.44) |
| 1 | 52 (206) | 82 (205) | 0.54 (0.38-0.76) |
| **Histology** | | | |
| Squamous | 30 (122) | 48 (121) | 0.48 (0.30-0.77) |
| Nonsquamous | 40 (161) | 57 (159) | 0.64 (0.43-0.96) |
| **Brain metastases at baseline** | | | |
| Yes | 4 (34) | 12 (34) | 0.17 (0.04-0.76) |
| No | 66 (249) | 93 (246) | 0.60 (0.44-0.83) |
| **Cancer stage at screening** | | | |
| Locally advanced | 9 (45) | 15 (42) | 0.48 (0.20-1.14) |
| Metastatic | 61 (238) | 90 (238) | 0.59 (0.43-0.82) |




**LIMITATIONS:** OS subgroup analyses were not powered to show a statistically significant difference between or within individual subgroups. Furthermore, none of the subgroup analyses were prespecified in the subset of patients with known PD-L1 ≥50%. Firm conclusions cannot be made based on these subgroup analyses.

Reprinted from *The Lancet,* Vol 397, Sezer A, 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. Pages 592-604, 2021, with permission from Elsevier. *None of the subgroup analyses were prespecified. ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; OS, overall survival.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

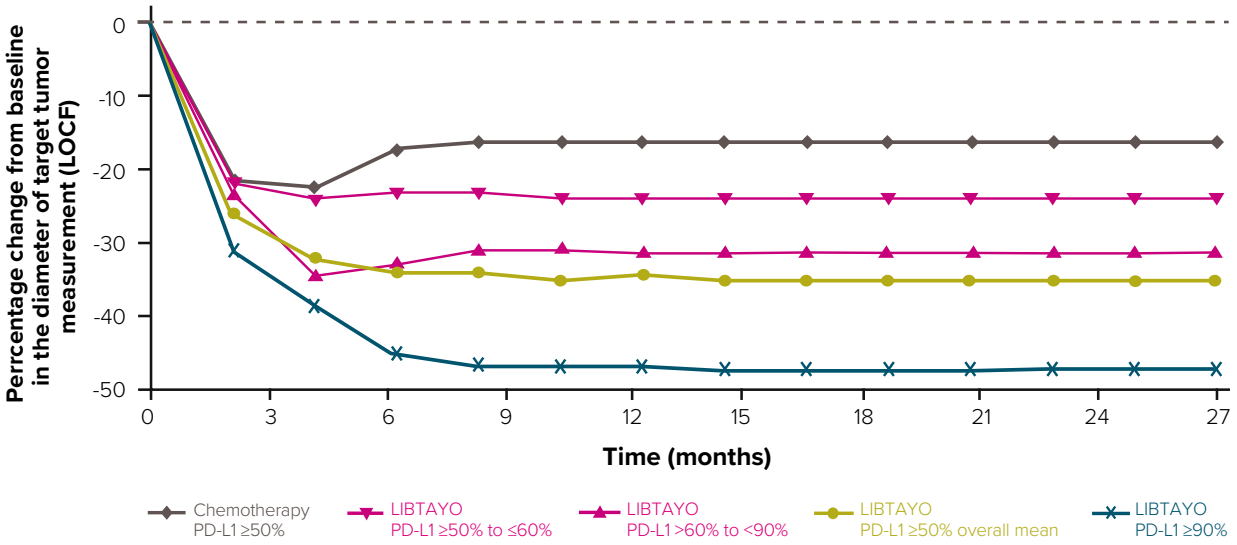
**Immune-mediated endocrinopathies:** For Grade 3 or 4 endocrinopathies, withhold until clinically stable or permanently discontinue depending on severity.

- **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

## In the subset of patients with advanced NSCLC who had no EGFR, ALK, or ROS1 aberrations and known PD-L1 ≥50% (n=563): Exploratory analysis of PD-L1 expression proportions[18]

**Figure 6. Change in Target Tumor Measurement with Baseline PD-L1 Proportion Scores**




**LIMITATIONS:** This is an exploratory analysis that was not powered to show a statistically significant difference between or within varying PD-L1 expression levels. Firm conclusions cannot be made based on these exploratory analyses.

Reprinted from *The Lancet,* Vol 397, Sezer A, 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. Pages 592-604, 2021, with permission from Elsevier. LOCF, last observation carried forward.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Immune-mediated endocrinopathies (cont'd):**

- **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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## In the subset of patients with advanced NSCLC who had no EGFR, ALK, or ROS1 aberrations and known PD-L1 ≥50% (n=563): Exploratory analysis of PD-L1 expression proportions[18] (cont'd)

**Table 3. Survival and Objective Response with Baseline PD-L1 Proportion Scores**

| | PD-L1 ≥90% | | PD-L1 >60% to <90% | | PD-L1 ≥50% to ≤60% | |
|---|---|---|---|---|---|---|
| **Number of Patients** | **LIBTAYO** (n=98) | Chemotherapy (n=94) | **LIBTAYO** (n=89) | Chemotherapy (n=90) | **LIBTAYO** (n=96) | Chemotherapy (n=96) |
| **Overall survival** | | | | | | |
| Median (95% CI), months | NR (17.3-NE) | 15.1 (11.1-NE) | 22.1 (17.9-NE) | 12.0 (9.6-19.2) | 21.9 (13.2-NE) | 14.0 (9.4-19.3) |
| HR (95% CI) | 0.46 (0.25-0.85) | | 0.47 (0.27-0.80) | | 0.77 (0.49-1.23) | |
| **Progression-free survival** | | | | | | |
| Median (95% CI), months | 15.3 (10.4-18.7) | 5.9 (4.3-6.2) | 6.2 (4.2-8.4) | 4.2 (4.1-5.7) | 4.3 (2.8-6.3) | 6.2 (5.0-6.2) |
| HR (95% CI) | 0.28 (0.17-0.46) | | 0.55 (0.38-0.80) | | 0.79 (0.56-1.12) | |
| **Tumor response** | | | | | | |
| Objective response rate (95% CI), % | 46 (36-56) | 18 (11-27) | 39 (29-50) | 20 (12-30) | 32 (23-43) | 23 (15-33) |

**LIMITATIONS:** This is an exploratory analysis that was not powered to show a statistically significant difference between or within varying PD-L1 expression levels. Firm conclusions cannot be made based on these exploratory analyses.

Reprinted from *The Lancet,* Vol 397, Sezer A, 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. Pages 592-604, 2021, with permission from Elsevier. HR, hazard ratio; NE, not evaluable; NR, not reached.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Immune-mediated endocrinopathies (cont'd):**

- **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
- **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

## LIBTAYO® (cemiplimab-rwlc) safety profile in EMPOWER-Lung 1[1]

The safety population of EMPOWER-Lung 1 included 697 patients with locally advanced or metastatic NSCLC (LIBTAYO [n=355], chemotherapy [n=342]).[1] LIBTAYO was permanently discontinued due to adverse reactions in 6% of patients; adverse reactions resulting in permanent discontinuation in at least 2 patients were pneumonitis, pneumonia, ischemic stroke, and increased aspartate aminotransferase. Adverse reactions of any grade occurring in ≥10% of patients are shown in **Table 4**, with those that occurred in ≥15% of patients in either treatment arm being musculoskeletal pain, rash, anemia, fatigue, and decreased appetite. Serious adverse reactions occurred in 28% of patients receiving LIBTAYO; the most frequent serious adverse events that occurred in at least 2% of patients were pneumonia and pneumonitis. Additionally, Grade 3 or 4 laboratory abnormalities worsening from baseline in ≥1% of patients receiving LIBTAYO in EMPOWER-Lung 1 are presented in **Table 5**.

**Table 4. Adverse Reactions in ≥10% of Patients Receiving LIBTAYO in EMPOWER-Lung 1[1]**

| | LIBTAYO (n=355) | | Chemotherapy (n=342) | |
|---|---|---|---|---|
| **Adverse Reactions** | **All Grades, %** | **Grade 3-4, %** | **All Grades, %** | **Grade 3-4, %** |
| Musculoskeletal pain* | 26 | 0.6 | 27 | 1.5 |
| Rash† | 15 | 1.4 | 6 | 0 |
| Anemia | 15 | 3.4 | 50 | 16 |
| Fatigue‡ | 14 | 1.1 | 26 | 2 |
| Decreased appetite | 12 | 0.6 | 18 | 0.3 |
| Pneumonia§ | 11 | 5 | 12 | 5 |
| Cough¶ | 11 | 0 | 8 | 0.3 |

Toxicity graded per NCI CTCAE v.4.03. *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. †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. ‡Fatigue is a composite term that includes fatigue, asthenia, and malaise. §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. ¶Cough is a composite term that includes cough and productive cough. CTCAE, Common Terminology Criteria for Adverse Events; NCI, National Cancer Institute.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Immune-mediated endocrinopathies (cont'd):**

- **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



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

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**Table 5. Grade 3 or 4 Laboratory Abnormalities Worsening From Baseline in ≥1% of Patients Receiving LIBTAYO (cemiplimab-rwlc) in EMPOWER-Lung 1[1]**

| Laboratory Abnormality | LIBTAYO (n=355) | Chemotherapy (n=342) |
|---|---|---|
| | Grade 3-4, %* | |
| **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 |

Toxicity graded per NCI CTCAE v.4.03. *Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter. CTCAE, Common Terminology Criteria for Adverse Events; NCI, National Cancer Institute.

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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.

## NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend cemiplimab-rwlc (LIBTAYO®) as a preferred systemic therapy option in advanced NSCLC

Cemiplimab-rwlc (LIBTAYO) is recommended by the NCCN Guidelines® for Non-Small Cell Lung Cancer as a Category 1* preferred systemic therapy option for patients with PD-L1–positive (≥50%) advanced NSCLC who are negative for actionable molecular markers and have no contraindications to PD-1 and PD-L1 inhibitors.[21]

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. To view the most recent and complete version of the guidelines, including other preferred options, go online to NCCN.org.

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

## Conclusion

LIBTAYO is approved for use as first-line monotherapy in patients with advanced NSCLC* with PD-L1 expression ≥50% of tumor cells and no EGFR, ALK, or ROS1 aberrations.[1] In one of the largest clinical trials of patients with advanced NSCLC expressing PD-L1 ≥50%, LIBTAYO demonstrated a statistically significant improvement in OS and PFS compared with chemotherapy.[1,18,20] Notably, there was a high percentage of patients randomized to receive chemotherapy who had disease progression and crossed over to receive treatment with LIBTAYO.[1,18,19] Furthermore, the EMPOWER-Lung 1 study included historically underrepresented populations; in the LIBTAYO arm (ITT population) at baseline, 12% of patients had treated and clinically stable brain metastases,† 18% had locally advanced disease, and 2% had controlled hepatitis B or C.[18,19]

*Patients with locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation or who have metastatic NSCLC. †Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization. Radiological confirmation of stability or response was not required.[1,18]

LIBTAYO is also approved in additional indications:

**APPROVED IN 2018**

**Advanced CSCC**

**Over 4 years of clinical treatment experience in patients with advanced CSCC[1,22,23,‡]**

- LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation[1]

**APPROVED IN 2021**

**Locally Advanced BCC**

- LIBTAYO is the **FIRST AND ONLY** treatment indicated for patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate[1]

‡LIBTAYO was FDA-approved in advanced CSCC in September 2018.[1,24]

# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

**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%). 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. 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.



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# Important Safety Information (cont'd)

## Warnings and Precautions (cont'd)

### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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

- In the pooled safety analysis of 810 patients, the most common adverse reactions (≥15%) with LIBTAYO were musculoskeletal pain, fatigue, rash, and diarrhea
- In the pooled safety analysis of 810 patients, the most common Grade 3-4 laboratory abnormalities (≥2%) with LIBTAYO were lymphopenia, hyponatremia, hypophosphatemia, increased aspartate aminotransferase, anemia, and hyperkalemia

## 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

**Please see accompanying full Prescribing Information.**

# Indications and Usage

LIBTAYO is indicated 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 indicated for the treatment of patients with metastaticcutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

LIBTAYO is indicated for the treatment of patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

## Notes





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