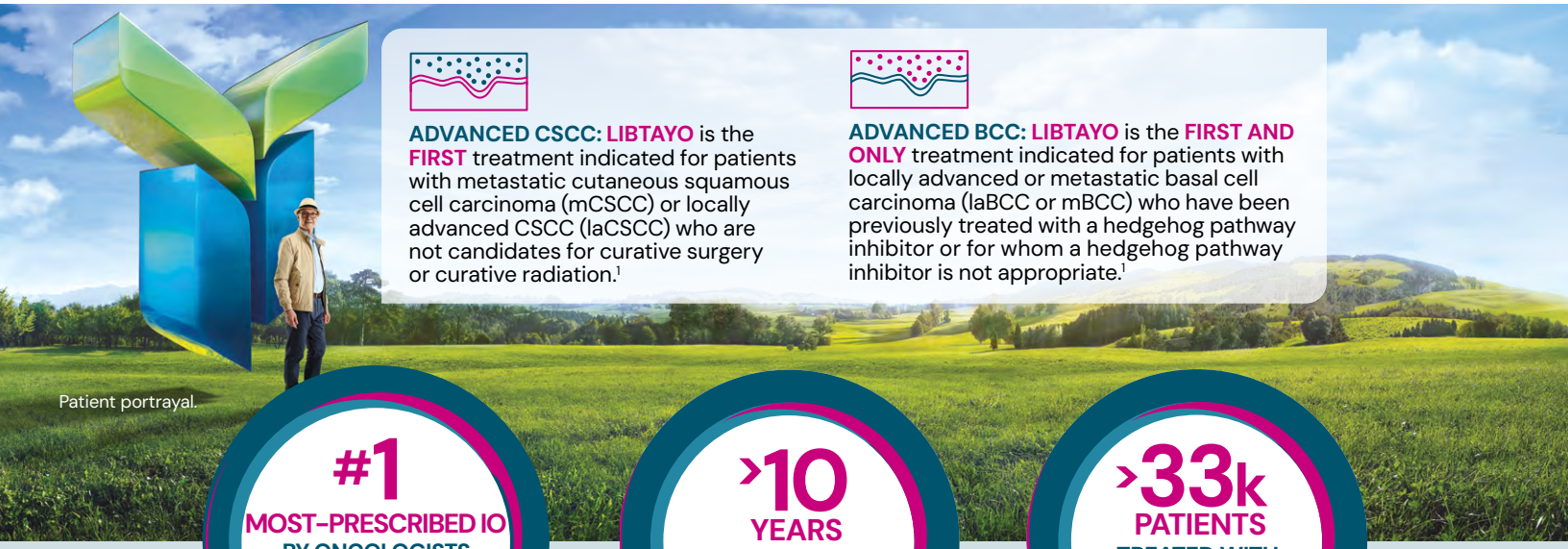
LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

EVIDENCE THAT EMPOWERS CHANGE

Empowering decision-making in patients with advanced CSCC and advanced BCC



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

ADVANCED BCC: LIBTAYO is the **FIRST AND ONLY** treatment indicated for patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.[1]

#1
MOST-PRESCRIBED IO BY ONCOLOGISTS ACROSS BOTH ADVANCED CSCC AND ADVANCED BCC[2]*†

>10
YEARS
OF CLINICAL TREATMENT EXPERIENCE[3]†

>33k
PATIENTS
TREATED WITH LIBTAYO ACROSS ALL INDICATIONS[2]‡

*Estimate based on IQVIA medical claims data from October 2018 through December 2024 and calibrated with actual vials sold.[2]
IO=immunotherapy.

†FDA approved in advanced CSCC in 2018. Includes clinical trial experience and postmarketing data.[1,3]

‡Since its first approval in 2018.[1] Estimate based on IQVIA medical claims data from October 2018 through December 2024 and calibrated with actual vials sold.[2]

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.

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

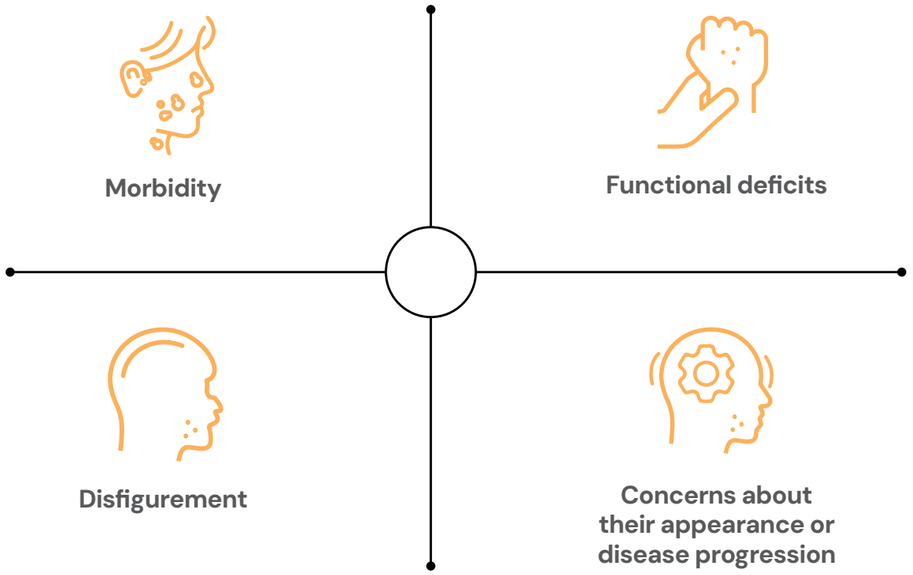
Advanced CSCC and advanced BCC can be complex and may lead to poor prognosis[4-6]

Every year in the United States,

~40,000 patients progress to aCSCC[7]

>20,000 patients progress to aBCC[8,9]

aCSCC and aBCC may have psychosocial and functional impact on patients[5,10-13]



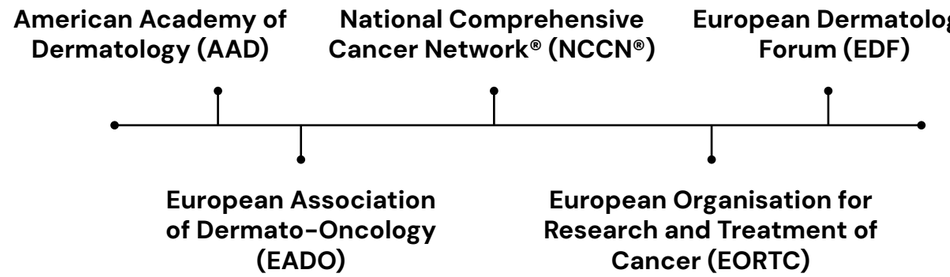
aBCC=advanced BCC; aCSCC=advanced CSCC.

Early patient identification and a multidisciplinary treatment approach are vital for improving aCSCC and aBCC outcomes[5,14-17]

Collaboration among different specialists is recommended to discuss the appropriate course of action for patients with certain characteristics[16-19]:

- Reradiation
- Unresectable or inoperable disease
- Invasion of surrounding tissue
- Multiple recurrences
- Residual disease after multiple surgeries
- Lack of response to systemic treatment
- Intolerance to systemic treatment
- Disease progression on systemic treatment

Guidelines unanimously recommend working with a multidisciplinary team (eg, dermatologists, oncologists, and surgeons) for treating patients with aCSCC and aBCC[16-20]



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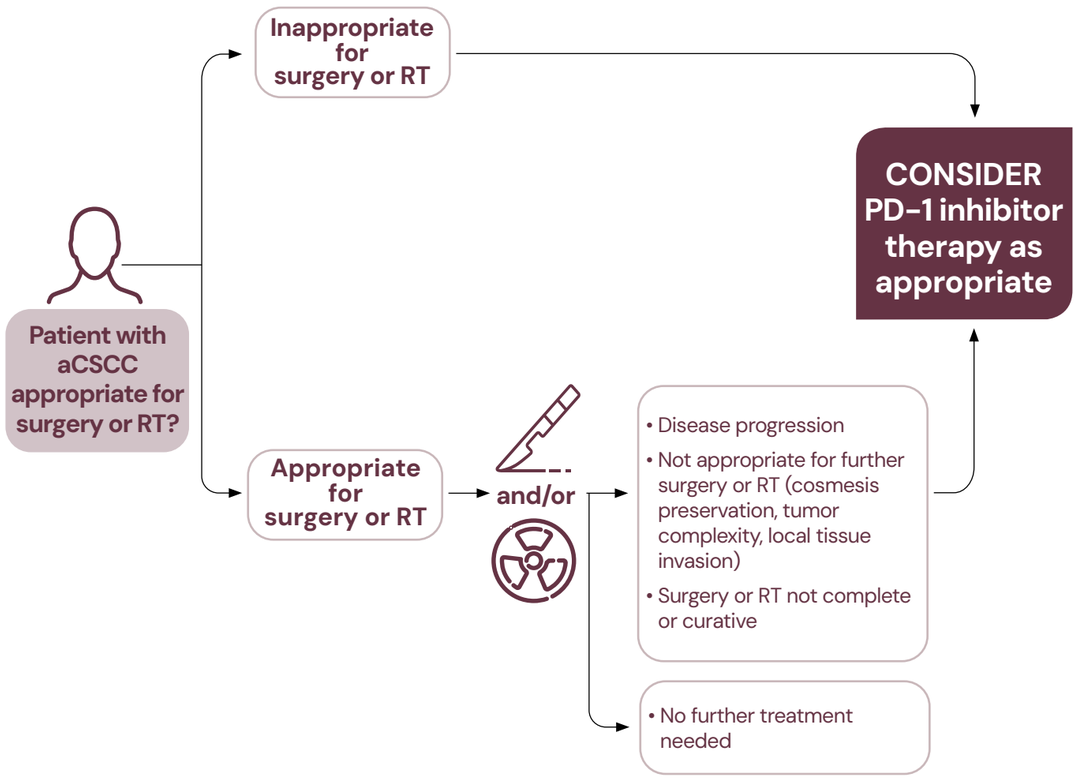
Consult and comanage with a multidisciplinary team to consider all appropriate treatment options for your patients with aCSCC and aBCC

aCSCC patients can benefit from a multidisciplinary approach[16]

Surgery and radiation are important treatment options but may not be appropriate for some patients with aCSCC[16,21–25]

Surgery may result in severe disfigurement or dysfunction in anatomically challenging locations, and radiation may cause acute and late toxicities[16,21,22]

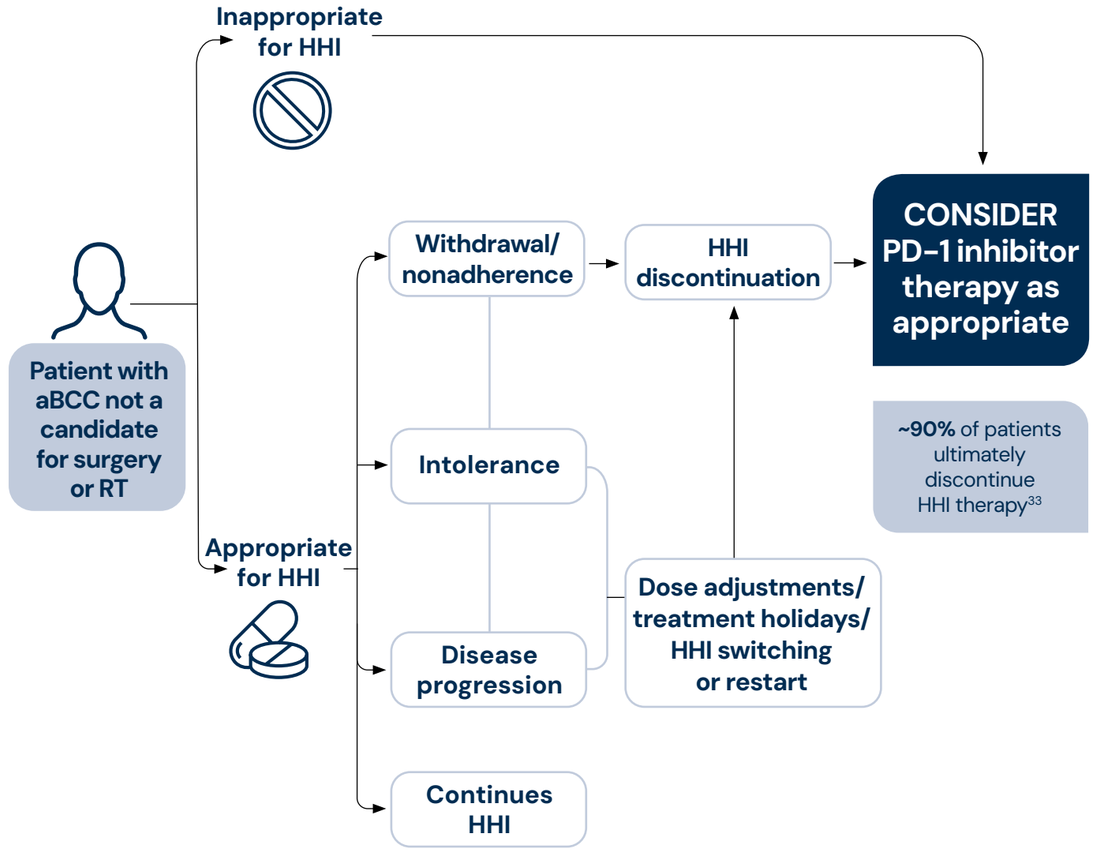


PD-1 inhibitor therapy could be a treatment option for your patients if surgery and RT are ruled out[36]

PD-1=programmed death receptor-1; RT=radiation therapy.

aBCC patients can benefit from a multidisciplinary approach[17]

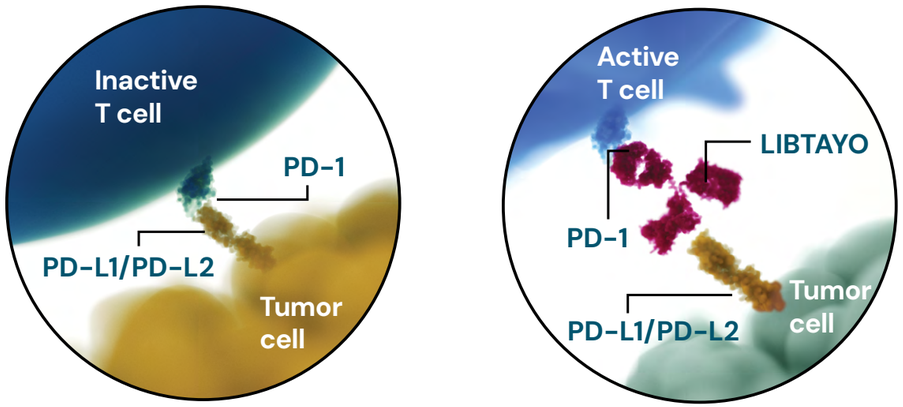
HHIs are an important step in the aBCC treatment algorithm, but many patients discontinue or are inappropriate for HHI therapy[26–36]



PD-1 inhibitor therapy could be an appropriate next step if HHIs are deemed inappropriate or permanently discontinued[36]

HHI=hedgehog pathway inhibitor.

LIBTAYO® (cemiplimab-rwlc) can help activate your patient's immune system to recognize, attack, and kill the cancer cells that have found ways to avoid the immune system[1]



Tumor immune evasion

T-cell inactivation can result from interaction of the PD-1 receptor on tumor-infiltrating T cells with its ligands, PD-L1 and PD-L2, expressed on tumor cells.

T-cell activity restored

LIBTAYO binds to PD-1 on T cells, blocking its interaction with PD-L1 and PD-L2 on tumor cells, helping to restore the antitumor T-cell response.

LIBTAYO is a PD-1 inhibitor, not chemotherapy or radiation therapy

PD-L1=programmed death-ligand 1; PD-L2=programmed death-ligand 2.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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.

Withhold or permanently discontinue LIBTAYO depending on severity of the adverse reaction (see Section 2 Dosage and Administration in the accompanying Full Prescribing Information). 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.

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

Cemiplimab-rwlc (LIBTAYO®) is an immunotherapy administered by oncologists and is recommended by national guidelines[1,18,19]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Squamous Cell Skin Cancer V.2.2025 recommend cemiplimab-rwlc (LIBTAYO®) as a preferred systemic therapy option for appropriate patients with advanced CSCC[18]*

NCCN Category 2A* preferred recommendation

NCCN RECOMMENDED CATEGORY 2A* OPTION FOR ADVANCED CSCC	Locally advanced CSCC	Regional CSCC	Distant metastatic CSCC or regionally recurrent CSCC‡
	When curative surgery and curative radiation therapy are not feasible†	When curative surgery and curative radiation therapy are not feasible	When curative surgery and curative radiation therapy are not feasible
	A preferred PD-1 inhibitor	**A preferred PD-1 inhibitor**	**A preferred PD-1 inhibitor**

NCCN Guidelines® for Basal Cell Skin Cancer V.2.2025 include cemiplimab-rwlc (LIBTAYO®) as a recommended systemic therapy option for appropriate patients with advanced BCC[19]*

NCCN Category 2A* recommended systemic therapy option

NCCN RECOMMENDED CATEGORY 2A* OPTION FOR ADVANCED BCC	Locally advanced BCC§	Nodal or distant metastatic BCC
	For patients previously treated with an HHI or for whom an HHI is not appropriate	For patients previously treated with an HHI or for whom an HHI is not appropriate
	Only recommended PD-1 inhibitor for appropriate patients with advanced BCC	

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*Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate. All recommendations are Category 2A unless otherwise specified.[18,19]
†If curative surgery and curative RT are not feasible, recommend multidisciplinary consultation to consider systemic therapy alone. Assessment of feasibility of radiation therapy should be made by a radiation oncologist.[18]
‡For complicated cases, consider multidisciplinary consultation.[18]
§Locally advanced disease is defined by those that have primary or recurrent extensive disease where surgery and/or radiation therapy may not result in a cure or would possibly produce a significant functional limitation.[19]

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Situations where LIBTAYO® (cemiplimab-rwlc) may be appropriate for patients with aCSCC and aBCC[1]

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

aBCC: LIBTAYO is the **FIRST AND ONLY** treatment indicated for patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.[1]

When surgery may not be appropriate for aCSCC and aBCC[2,16,19]*

Locally invasive disease:
Tumor extending into the underlying tissue, cartilage, bone, or nerve

Anatomically challenging location of disease:
- Periorbital lesions threatening the eye
- Nasal or auricular lesions requiring rhinectomy or auriculectomy

Recurrence:
Recurrence at the same site after 2 or more surgical procedures

Anticipation of substantial morbidity or deformity from surgery

Other:
- Patient refusal of surgery
- Other conditions deemed contraindicating for surgery

When RT may not be appropriate for aCSCC and aBCC[2,16,19]*

Anatomically challenging location of disease:
Locations for which RT would be associated with unacceptable toxicity risk

Prior treatment:
Further RT would exceed the threshold of acceptable cumulative dose

Other:
- Patient refusal of RT
- Clinical judgment that tumor would be unlikely to respond to RT
- Other conditions deemed contraindicating for RT

When HHIs may not be appropriate for aBCC[2,26-36]*

Prior progression of disease on HHIs Based on clinician judgment

Intolerable HHI-related adverse events

*Assessment by individual physician or surgeon may vary.

Important Safety Information (continued)
Warnings and Precautions (continued)
Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids. Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

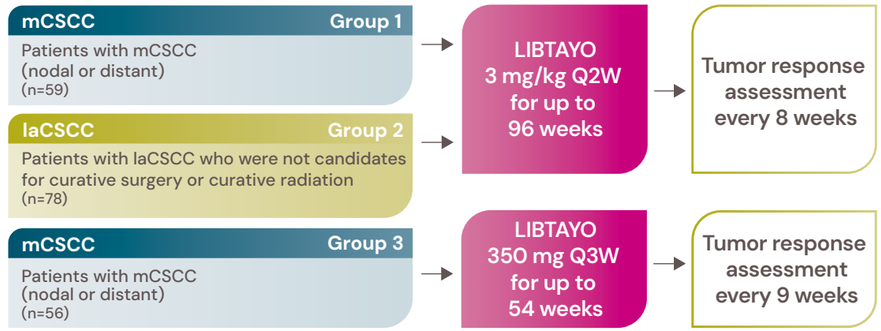
The incidence and severity of immune-mediated adverse reactions were similar when LIBTAYO was administered as a single agent or in combination with chemotherapy.

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

LIBTAYO was validated in the largest prospective clinical trial for advanced CSCC[1,37-45]

Study 1540 was a global, pivotal, open-label, nonrandomized, multicohort study in patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation[1]

Study 1540 trial design (N=193)[1]



Primary endpoint[1]:
- Confirmed ORR as assessed by ICR

Secondary endpoints included[2]:
- DOR
- CR rate
- Safety and tolerability

Study 1540—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included 193 patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation (targeted enrollment). Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 96 weeks or LIBTAYO 350 mg every 3 weeks for up to 54 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]

Study 1540 excluded patients with autoimmune disease who required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/PD-L1–blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or ECOG PS ≥2.[1]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months.[1]

In Study 1540, 66% of patients received LIBTAYO as first-line systemic therapy, 81% had received prior cancer-related surgery, and 68% had received any prior radiotherapy. Of patients with mCSCC, 23% had only nodal metastases and 77% had distant metastases. No PD-L1 testing is required before starting LIBTAYO for advanced CSCC.[1,46]

CR=complete response; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group performance status; ICR=independent central review; ORR=objective response rate; Q2W=every 2 weeks; Q3W=every 3 weeks.

Important Safety Information (continued)
Warnings and Precautions (continued)
Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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 2.6% (33/1281) of patients receiving LIBTAYO, including Grade 4 (0.3%), Grade 3 (0.6%), and Grade 2 (1.6%). Pneumonitis led to permanent discontinuation in 1.3% of patients and withholding of LIBTAYO in 1.4% of patients.

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

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LIBTAYO® (cemiplimab-rwlc) is a proven treatment choice in advanced CSCC[1]

Efficacy results of Study 1540 for patients with mCSCC or laCSCC who were not candidates for curative surgery or radiation[1]*

mCSCC: 3 mg/kg Q2W (n=59)

51% ORR (95% CI, 37%-64%)

- Median duration of follow-up was 18.5 months (range, 1.1-41.0)[1,2]

laCSCC: 3 mg/kg Q2W (n=78)

45% ORR (95% CI, 34%-57%)

- Median duration of follow-up was 15.5 months (range, 0.8-43.2)[1,2]

mCSCC 350 mg Q3W (n=56)

46% ORR (95% CI, 33%-60%)

- Median duration of follow-up was 17.3 months (range, 0.6-43.4)[1,2]

All cohorts combined (N=193)

47% ORR (95% CI, 40%-54%)

- Median duration of follow-up was 15.7 months (range, 0.6-43.2)[1,2]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months.[1]

ORR was determined by the proportion of patients with best overall response of CR or PR based on ICR evaluation, as determined by RECIST version 1.1 for radiologic assessments, or by modified WHO Criteria for photographic assessments, or by the composite response criteria for patients assessed by both radiology and photography.[2]

PR was defined as a decrease of ≥30% in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. PR of externally visible disease was defined as a decrease of ≥50% in the sum of products of perpendicular longest diameters of target lesions, per WHO Criteria. Nontarget lesions could not have PD, and there could be no new lesions. Responses had to be maintained for at least 4 weeks.[2]

CR was defined as a disappearance of all target lesions for at least 4 weeks. Nontarget lesions also had to show a CR, and there could be no new lesions. Any pathological lymph nodes (whether target or nontarget) must have shown a reduction in short axis to <10 mm (<1 cm). Only includes patients with complete healing of prior cutaneous involvement; patients with laCSCC in Study 1540 required biopsy to confirm a CR.[2]

*Data cutoff was March 2022.[47]
CI=confidence interval; PD=progressive disease; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; WHO=World Health Organization.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated pneumonitis (continued): Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 61% of the 33 patients. Of the 18 patients in whom LIBTAYO was withheld, 10 reinitiated after symptom improvement; of these, 4/10 (40%) had recurrence of pneumonitis.

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.

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

LIBTAYO demonstrated clinically meaningful and durable responses in advanced CSCC[1]*

Median DOR in Study 1540

mCSCC: 3 mg/kg Q2W (n=59)

Median DOR: not reached
(range, 2.8-38.9 months; n=30)

93%	77%
of responders (n=28) had a DOR ≥6 months	of responders (n=23) had a DOR ≥12 months

- Median duration of follow-up was 18.5 months (range, 1.1-41.0)[1,2]

laCSCC: 3 mg/kg Q2W (n=78)

Median DOR: 42 months
(range, 1.9-54.6 months; n=35)

89%	69%
of responders (n=31) had a DOR ≥6 months	of responders (n=24) had a DOR ≥12 months

- Median duration of follow-up was 15.5 months (range, 0.8-43.2)[1,2]

mCSCC: 350 mg Q3W (n=56)

Median DOR: 41 months
(range, 4.2-46.3 months; n=26)

96%	88%
of responders (n=25) had a DOR ≥6 months	of responders (n=23) had a DOR ≥12 months

- Median duration of follow-up was 17.3 months (range, 0.6-43.4)[1,2]

All cohorts combined (N=193)

Median DOR: 41 months
(range, 1.9-54.6 months; n=91)

92%	77%
of responders (n=84) had a DOR ≥6 months	of responders (n=70) had a DOR ≥12 months

- Median duration of follow-up was 15.7 months (range, 0.6-43.2)[1,2]

Median TTR was rapid at 2.1 months (range, 1.7 to 22.8 months) for all cohorts combined, based on an open-label, single-arm trial that did not include comparisons to other treatments[1,2†]

*Data cutoff was March 2022.[47]
†First assessment was performed at 8 weeks.[2]
TTR=time to response.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated colitis (continued): Immune-mediated colitis occurred in 2% (25/1281) of patients receiving LIBTAYO, including Grade 3 (0.8%) and Grade 2 (0.9%). Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBTAYO in 1.2% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 56% of the 25 patients. Of the 16 patients in whom LIBTAYO was withheld, 6 reinitiated LIBTAYO after symptom improvement; of these, 4/6 (67%) had recurrence

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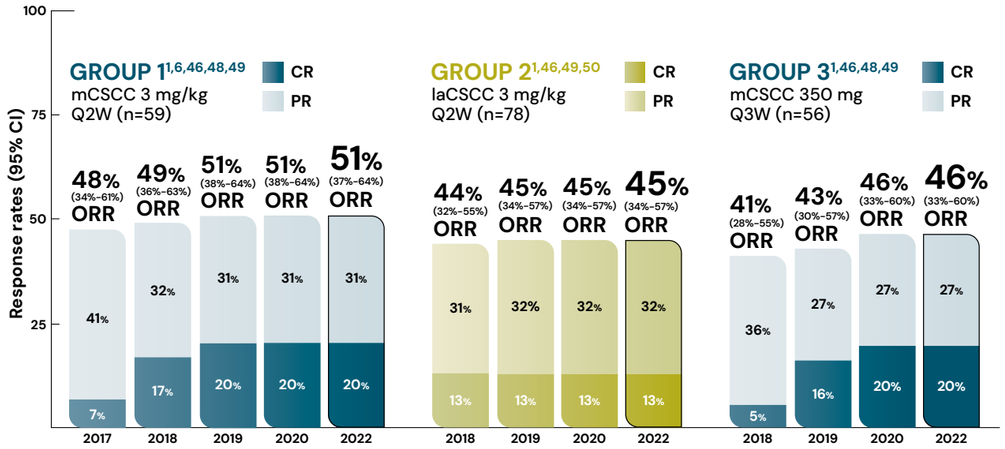
LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) over time: Continued efficacy demonstrated across data readouts in Study 1540[1,2*]

Response rates over time in patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation[1,2]

The following data represent 5 years of follow-up for Group 1 and 4 years of follow-up for Group 2 and Group 3. Follow-ups for each group are based on time from primary analysis.[1,2]

Median duration of follow-up: mCSCC 3 mg/kg Q2W—18.5 months (range, 1.1-41.0); laCSCC 3 mg/kg Q2W—15.5 months (range, 0.8-43.2); mCSCC 350 mg Q3W—17.3 months (range, 0.6-43.4).[1,2]



Durable responses demonstrated across data readouts[1,6,46,48-50*]

Median DOR[1]

NOT REACHED
(range, 2.8-38.9; n=30)

42 MONTHS
(range, 1.9-54.6; n=35)

41 MONTHS
(range, 4.2-46.3; n=26)

*Response rates and duration of response are based on analysis by ICR of Study 1540 at time of data cutoff: March 2022.[1,2,47]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

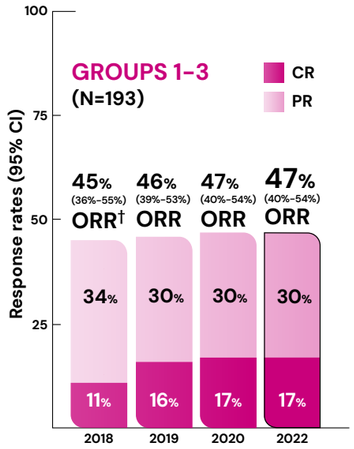
Immune-mediated hepatitis: LIBTAYO can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2.4% (31/1281) of patients receiving LIBTAYO, including fatal (<0.1%), Grade 4 (0.3%), Grade 3 (1.6%), and Grade 2 (0.2%). Hepatitis led to permanent discontinuation of LIBTAYO in 1.4% of patients and withholding of LIBTAYO in 0.7% of patients. Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 13% (4/31) of these patients. Hepatitis resolved in 39% of the 31 patients. Of the 9 patients in whom LIBTAYO was withheld, 5 reinitiated LIBTAYO after symptom improvement; of these, 1/5 (20%) had recurrence.

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

LIBTAYO delivered clinically meaningful responses in all cohorts combined[1,2,46-49*]

Response rates over time (N=193)[1,46,48,49]

Median duration of follow-up: 15.7 months (range, 0.6-43.2).[1,2]



With each of these data readouts, LIBTAYO continued to demonstrate durable responses in patients with advanced CSCC[1,2]

Among responders, median time to CR[51‡]
11.2 months
(IQR, 7.4–14.8; n=31)

Median DOR[1*]

41 MONTHS
(range, 1.9-54.6; n=91)

*Response rates and duration of response are based on analysis by ICR of Study 1540 at time of data cutoff: March 2022.[1,2,47]
†Combined median ORR for 2018 is derived from 115 patients in Groups 1 and 3.[48]
‡Median time to CR is derived from 31 complete responders. No firm conclusions can be drawn because results are from an aggregation of additional, pooled, long-term data from the original study groups of the phase 2, open-label, non-randomized, multicenter study.[51]
IQR=interquartile range.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies:

- **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 0.5% (6/1281) of patients receiving LIBTAYO, including Grade 3 (0.5%). Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient. LIBTAYO was withheld in 1 (<0.1%) patient due to adrenal insufficiency and not reinitiated. Systemic corticosteroids were required in 83% (5/6) patients with adrenal insufficiency; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency had resolved in 17% of the 6 patients

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LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Meaningful tumor reduction in clinical trial patients with mCSCC[2]

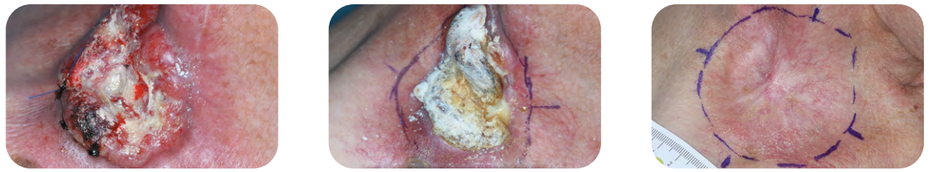
85-year-old male with mCSCC; supraclavicular lesion with distant metastasis[2]*

Supra-clavicular Lesion

Individual patient responses may vary. This is an example from the 30% of patients who had a PR in the combined analysis of patients who received LIBTAYO® (cemiplimab-rwlc) in Study 1540.[1]

The duration of response for this patient was 36.57+ months. At data cutoff, he had completed his treatment per protocol, and was in his 16th month of posttreatment follow-up. At this time, his response was still ongoing.[2]

Screening | **After 8 weeks** | **After 56 weeks**



Actual clinical trial patient.

Clinical outcomes (as of data cutoff March 2022)[2,47]

- **Best overall response:** PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- **Time to response:** 8 weeks (1.74 months)
- **Duration of response:** 36.57+ months

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 3 mg/kg every 2 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[2]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **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 0.5% (7/1281) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.3%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient and withholding of LIBTAYO in 2 (0.2%) patients. Systemic corticosteroids were required in 86% (6/7) of patients with hypophysitis. Hypophysitis resolved in 14% of the 7 patients. Of the 2 patients in whom LIBTAYO was withheld for hypophysitis, none of the patients reinitiated

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

Meaningful tumor reduction in clinical trial patients with laCSCC[2]

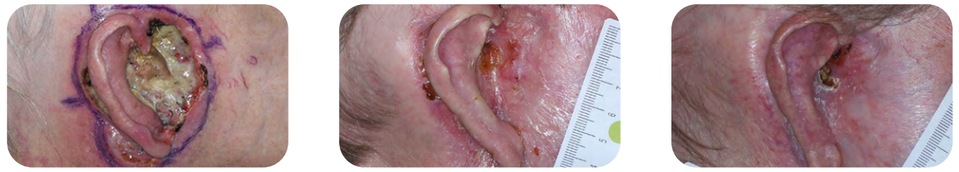
57-year-old male with laCSCC who was not a candidate for curative surgery or curative radiation. Patient pictured suffered from a lesion in which the clinical judgment was that the tumor would be unlikely to respond to RT[2]*

Interior Auricular Lesion

Individual patient responses may vary. This is an example from the 30% of patients who had a PR in the combined analysis of patients who received LIBTAYO in Study 1540.[1]

The duration of response for this patient was 20.5 months. At data cutoff, he had completed his treatment per protocol, and was in his 3rd month of posttreatment follow-up. At this time, he was no longer in response due to having progressive disease.[2]

Screening | **After 24 weeks** | **After 88 weeks**



Actual clinical trial patient.

Clinical outcomes (as of data cutoff March 2022)[2,47]

- **Best overall response:** PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- **Time to response:** 24 weeks (5.55 months)
- **Duration of response:** 20.5 months

*Patient received LIBTAYO 3 mg/kg every 2 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[2]

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
- **Thyroiditis:** Thyroiditis occurred in 0.6% (8/1281) of patients receiving LIBTAYO, including Grade 2 (0.3%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 (<0.1%) patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis resolved in 13% of the 8 patients. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

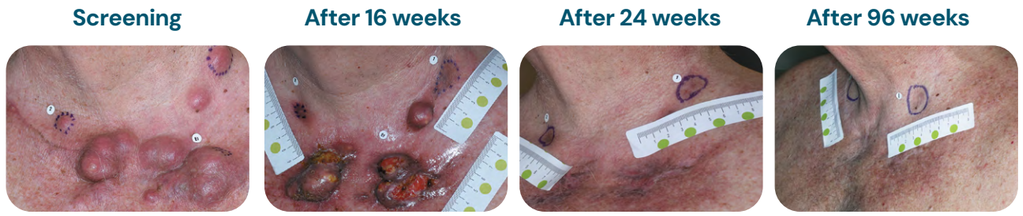
Meaningful tumor reduction in clinical trial patients with mCSCC[2]

66-year-old male with mCSCC who was not a candidate for curative surgery or curative radiation. Patient pictured suffered from numerous periclavicular lesions[2]*

Numerous Periclavicular Lesions

Individual patient responses may vary. This is an example from the 17% of patients who had a CR in the combined analysis of patients who received LIBTAYO® (cemiplimab-rwlc) in Study 1540.[1]

The duration of response for this patient was 31.08+ months. At data cutoff, he had completed his treatment per protocol. At that time, his response was still ongoing.[2,47]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff March 2022)[2,47]

- **Best overall response:** CR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- **Time to response:** 24 weeks (5.55 months)
- **Duration of response:** 31.08+ months

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 3 mg/kg every 2 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[2]

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% (39/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 7 (0.5%) patients due to hyperthyroidism. Systemic corticosteroids were required in 8% (3/39) of patients. Hyperthyroidism resolved in 56% of 39 patients. Of the 7 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism

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

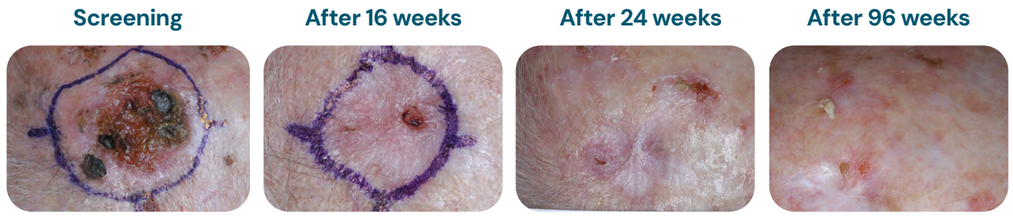
Meaningful tumor reduction in clinical trial patients with laCSCC[2]

70-year-old male with laCSCC who was not a candidate for curative surgery or curative radiation. Patient pictured suffered from invasive disease and radiotherapy was contraindicated[2]*

Cranial Lesion

Individual patient responses may vary. This is an example from the 30% of patients who had a PR in the combined analysis of patients who received LIBTAYO in Study 1540.[1]

The duration of response for this patient was 28.81 months. At data cutoff, he had completed his treatment per protocol, and was in his 9th month of posttreatment follow-up. At this time, he was no longer in response due to having progressive disease.[2]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff March 2022)[2,47]

- **Best overall response:** PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- **Time to response:** 16 weeks (3.71 months)
- **Duration of response:** 28.81 months

*Patient received LIBTAYO 3 mg/kg every 2 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[2]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Hypothyroidism:** Hypothyroidism occurred in 7% (87/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 3 (0.2%) patients. Hypothyroidism led to withholding of LIBTAYO in 9 (0.7%) patients. Systemic corticosteroids were required in 1.1% (1/87) of patients with hypothyroidism. Hypothyroidism resolved in 6% of the 87 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 and did not have recurrence of hypothyroidism

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) demonstrated a favorable safety profile in patients with advanced CSCC in Study 1540[1]

Adverse reactions (ARs) in ≥10% of patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation, and who received LIBTAYO in Study 1540[1]

Adverse reactions	Advanced CSCC (N=358)	
	All grades, %	Grades 3-4, %
General disorders and administration site		
Fatigue*	38	2.2
Skin and subcutaneous tissue		
Rash†	34	1.7
Pruritus‡	22	0.3
Actinic keratosis	10	0
Musculoskeletal and connective tissue		
Musculoskeletal pain§	33	2.5
Gastrointestinal		
Diarrhea‖	26	1.1
Nausea	21	0
Constipation	13	0.3
Vomiting¶	11	0.6
Infections and infestations		
Upper respiratory tract infection#	14	1.1
Skin infection**	11	4.5
Respiratory		
Cough††	12	0
Metabolism and nutrition		
Decreased appetite	11	0.6
Nervous system disorders		
Headache‡‡	10	0
Dizziness§§	10	0.3

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03.[1]

*Fatigue is a composite term that includes fatigue and asthenia.[1]

†Rash is a composite term that includes rash, rash maculopapular, dermatitis, erythema, eczema, dermatitis bullous, rash erythematous, dermatitis acneiform, psoriasis, dermatitis contact, blister, pemphigoid, rash papular, hand dermatitis, skin exfoliation, autoimmune dermatitis, rash pruritic, rash macular, rash pustular, urticaria, dermatitis atopic, drug eruption, eczema asteatotic, skin reaction, dermatitis psoriasiform, eczema nummular, exfoliative rash, and immune-mediated dermatitis.[1]

‡Pruritus is a composite term that includes pruritus and pruritus allergic.[1]

§Musculoskeletal pain is a composite term that includes arthralgia, back pain, myalgia, polyarthritis, pain in extremity, neck pain, non-cardiac chest pain, arthritis, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal stiffness, bone pain, immune-mediated arthritis, and spinal pain.[1]

‖Diarrhea is a composite term that includes diarrhea, colitis, and autoimmune colitis.[1]

¶Vomiting is a composite term that includes hematemesis and vomiting.[1]

#Upper respiratory tract infection is a composite term that includes upper respiratory tract infection, nasopharyngitis, sinusitis, influenza-like illness, rhinitis, influenza, viral upper respiratory tract infection, respiratory tract infection, influenza A virus test positive, and pharyngitis.[1]

**Skin infection is a composite term that includes skin infection, cellulitis, fungal skin infection, and staphylococcal skin infection.[1]

††Cough is a composite term that includes cough, productive cough, and upper airway cough syndrome.[1]

‡‡Headache is a composite term that includes headache, sinus headache, and migraine.[1]

§§Dizziness is a composite term that includes dizziness, vertigo, vertigo positional, and dizziness postural.[1]

In 26 patients with advanced CSCC treated with LIBTAYO in Study 1423, safety data were consistent with those described above from Study 1540.[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, see additional Important Safety Information throughout and in Section 5 of the accompanying full Prescribing Information.

Grade 3 or 4 laboratory abnormalities in patients with advanced CSCC in Study 1540[1]

Grade 3 or 4 laboratory abnormalities worsening from baseline in ≥1% of patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation and who received LIBTAYO

Laboratory abnormality	Advanced CSCC (N=358) Grades 3-4, %*
Hematology	
Lymphopenia	7.0
Anemia	4.1
Electrolytes	
Hyponatremia	4.9
Hypophosphatemia	4.1
Hypercalcemia	2.0
Hypokalemia	1.5
Coagulation	
Increased INR	2.9
Chemistry	
Increased aspartate aminotransferase	1.5
Hypoalbuminemia	1.2

- The most common (≥20%) ARs were fatigue, rash, musculoskeletal pain, diarrhea, pruritus, and nausea[1]
- The most common Grade 3 or 4 ARs (≥2%) were hypertension, skin infection, pneumonia, anemia, fatigue, musculoskeletal pain, and pneumonitis. The most common (≥4%) Grade 3 or 4 laboratory abnormalities worsening from baseline were lymphopenia, hyponatremia, anemia, and hypophosphatemia[1]
- Serious ARs occurred in 41% of patients[1]
- Serious ARs that occurred in at least 2% of patients were pneumonia (3.6%), skin infection (3.6%), and pneumonitis (2.8%)[1]
- Fatal ARs occurred in 5% of patients who received LIBTAYO, including deaths due to infections (2.2%)[1]
- LIBTAYO was permanently discontinued due to ARs in 12% of patients[1]
- ARs resulting in permanent discontinuation in at least 2 patients were pneumonitis, rash, confusional state, general physical health deterioration, hemorrhage, liver function test abnormalities, and musculoskeletal pain[1]
- Dosage interruptions of LIBTAYO due to an AR occurred in 36% of patients. ARs which required dosage interruption in ≥2% of patients included diarrhea, infusion-related reaction, upper respiratory tract infection, liver function test abnormalities, musculoskeletal pain, pneumonitis, and rash[1]

Toxicity graded per NCI CTCAE v.4.03.[1]

*Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter.[1]

INR=international normalized ratio.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **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% (1/1281) of patients (Grade 4). No patient discontinued treatment due to Type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients, treatment was reinitiated after symptom improvement. Patient received long-term insulin therapy

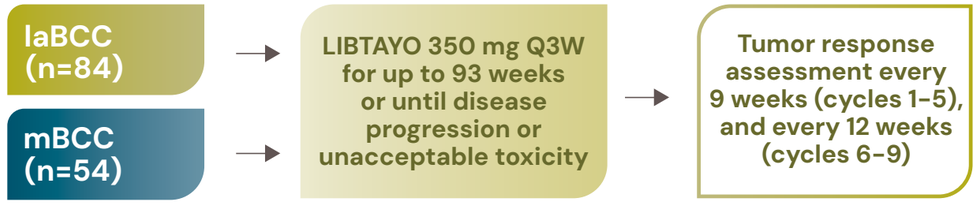
Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

In patients with advanced BCC previously treated with an HHI,

LIBTAYO® (cemiplimab-rwlc) was validated in the largest prospective clinical trial for a PD-1 inhibitor[1]

Study 1620 trial design[1]



Primary endpoint[1]:
- Confirmed ORR as assessed by ICR

Secondary endpoints included[2]:
- DOR
- CR rate
- Safety and tolerability

Study 1620 was an open-label, multicenter, phase 2, nonrandomized study that included 138 patients with laBCC or mBCC who had progressed on HHI therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1,2]

Study 1620 excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/PD-L1 therapy or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or ECOG PS ≥2.[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 0.7% (9/1281) of patients receiving LIBTAYO, including fatal (<0.1%), Grade 3 (<0.1%), and Grade 2 (0.5%). Nephritis led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 0.4% of patients. Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in 78% of the 9 patients. Of the 5 patients in whom LIBTAYO was withheld, 4 reinitiated LIBTAYO after symptom improvement; of these, 1/4 (25%) had recurrence.

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 1.9% (24/1281) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (0.8%).

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

Proven and durable responses in both laBCC and mBCC[1]

In patients with laBCC previously treated with an HHI[1]

32% ORR* (95% CI, 22%–43%)

- Median duration of follow-up was 15.9 months (range, 0.5–39.7)[1,2]

laBCC

Median DOR: **Not Reached** (range, 2.1–36.8+ months; n=27)

85% of responders (n=23/27) had a DOR ≥6 months

In patients with mBCC previously treated with an HHI[1]

22% ORR* (95% CI, 12%–36%)

- Median duration of follow-up was 8.4 months (range, 1.5–36.2)[1,2]

mBCC

Median DOR: **16.7 months** (range, 9.0–25.8+ months; n=12)

100% of responders (n=12/12) had a DOR ≥6 months

Median TTR was 4.3 months (range, 2.1–21.4 months) for laBCC and 3.1 months (range, 2.0–10.5 months) for mBCC.[1]

At the 1-year post–primary analysis data readout[1,2],
- Percentage of patients with laBCC responding to LIBTAYO (ORR) increased from 29% at primary analysis to 32%
- Median DOR had not been reached for patients with laBCC who responded to LIBTAYO

ORR was determined by the proportion of patients with best overall response of CR or PR based on ICR evaluation, as determined by RECIST version 1.1 for radiologic assessments, or by modified WHO Criteria for photographic assessments, or by the composite response criteria for patients assessed by both radiology and photography.[2]

CR was defined as a disappearance of all target lesions for at least 4 weeks. Nontarget lesions also had to be a CR and there could be no new lesions. Any pathological lymph nodes (whether target or nontarget) must have reduction in short axis to <10 mm (<1 cm). Only includes patients with complete healing of prior cutaneous involvement; patients with laBCC in the study required biopsy to confirm CR.[2]

PR was defined as a decrease of ≥30% in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. PR of externally visible disease is defined as a decrease of ≥50% in the sum of products of perpendicular longest diameters of target lesions per WHO Criteria. Nontarget lesions could not have PD, and there could be no new lesions. Responses had to be maintained for at least 4 weeks.[2]

*Data cutoff was May 2021.[2]

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 0.2% of patients and withholding of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 71% of the 24 patients.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

In a study of patients with laBCC previously treated with an HHI,

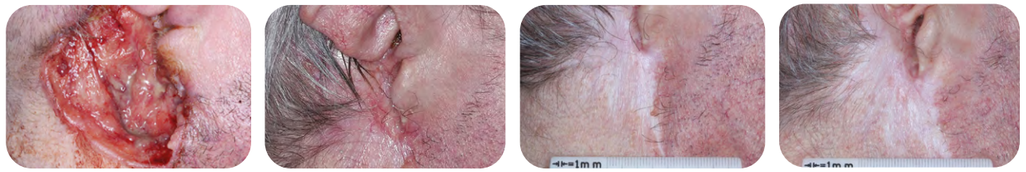
Clinically meaningful tumor reduction observed after treatment with LIBTAYO® (cemiplimab-rwlc)[2]

79-year-old man with laBCC who had discontinued prior vismodegib due to disease progression[2]*

Right Auricular Lesion

Individual patient responses may vary.
This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[1]

Screening	After 18 weeks	After 81 weeks	After 104 weeks



Actual clinical trial patient.

Clinical outcomes (as of data cutoff May 20, 2021)[2]

- **Best overall response:** PR by composite evaluation (RECIST 1.1 + WHO Criteria) per ICR
- **Time to response:** 4.2 months
- **Duration of response (DOR):** 32.36+ months

The ORR in Study 1620 was 32% in patients with laBCC and median DOR was not reached (range, 2.1-36.8+ months).[1]

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 350 mg every 3 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated dermatologic adverse reactions (continued): Of the 17 patients in whom LIBTAYO was withheld for dermatologic adverse reaction, 13 reinitiated LIBTAYO after symptom improvement; of these, 5/13 (38%) had recurrence of the dermatologic adverse reaction. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 1281 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.

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

In a study of patients with laBCC previously treated with an HHI,

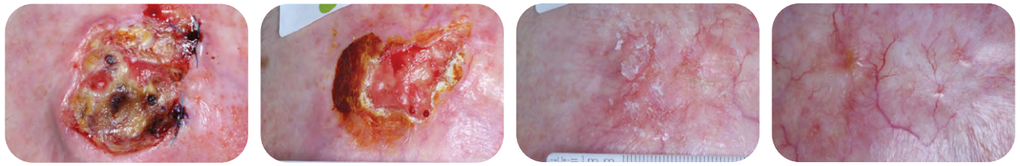
Clinically meaningful tumor reduction observed after treatment with LIBTAYO[2]

66-year-old man with laBCC who had discontinued prior vismodegib due to intolerance[2]*

Right Cranial Lesion

Individual patient responses may vary.
This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[1]

Screening	After 9 weeks	After 18 weeks	After 101 weeks



Actual clinical trial patient.

Clinical outcomes (as of data cutoff May 20, 2021)[2]

- **Best overall response:** PR by composite evaluation (RECIST 1.1 + WHO Criteria) per ICR
- **Time to response:** 2.1 months
- **Duration of response:** 29.93+ months

The ORR in Study 1620 was 32% in patients with laBCC and median DOR was not reached (range, 2.1-36.8+ months).[1]

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 350 mg every 3 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions (continued):

- **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

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

In a study of patients with laBCC previously treated with an HHI,

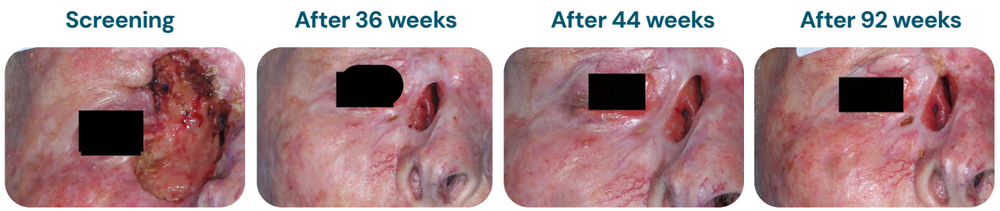
Clinically meaningful tumor reduction observed after treatment with LIBTAYO® (cemiplimab-rwlc)[2]

77-year-old woman with laBCC who discontinued prior vismodegib due to disease progression[2]*

Right Nasal Cavity Lesion

Individual patient responses may vary.
This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[1]

The duration of response for this patient was 4.8 months. At the time of data cutoff, this patient was no longer in response due to having progressive disease.[2]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff May 20, 2021)[2]

- **Best overall response:** PR by composite evaluations (RECIST 1.1 + WHO Criteria) per ICR
- **Time to response:** 8.2 months
- **Duration of response:** 4.8 months

The ORR in Study 1620 was 32% in patients with laBCC and median DOR was not reached (range, 2.1-36.8+ months).[1]

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 350 mg every 3 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions (continued):

- **Musculoskeletal and connective tissue:** Myositis/polymyositis/dermatomyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
- **Endocrine:** Hypoparathyroidism
- **Other (hematologic/immune):** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis (HLH), systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection

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

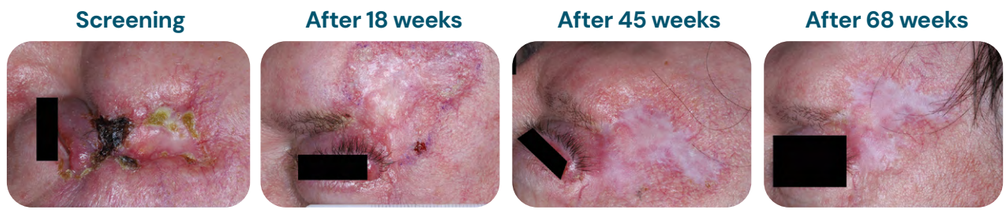
In a study of patients with laBCC previously treated with an HHI,

Clinically meaningful tumor reduction observed after treatment with LIBTAYO[2]

49-year-old man with laBCC who discontinued prior vismodegib due to disease progression[2]*

Left Periorbital Lesion

Individual patient responses may vary.
This is an example from the 7% of patients with laBCC who had a CR in Study 1620.[1]



Actual clinical trial patient.

Actual clinical trial patient.

Clinical outcomes (as of data cutoff May 20, 2021)[2]

- **Best overall response:** CR by composite evaluation (RECIST 1.1 + WHO Criteria) per ICR
- **Time to response:** 4.2 months
- **Duration of response:** 23.82+ months

The ORR in Study 1620 was 32% in patients with laBCC and median DOR was not reached (range, 2.1-36.8+ months).[1]

Plus sign (+) denotes ongoing at last assessment.[1]

*Patient received LIBTAYO 350 mg every 3 weeks. Please refer to the study design for the recommended dosage of LIBTAYO.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

Infusion-Related Reactions

Severe or life-threatening infusion-related reactions occurred in 0.2% of patients receiving LIBTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. Common symptoms of infusion-related reaction include nausea, pyrexia, and vomiting. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) demonstrated a favorable safety profile in Study 1620[1]

ARs in ≥10% of patients	LIBTAYO (N=138)	
	All Grades, %	Grades 3-4, %
General disorders and administration site conditions		
Fatigue*	50	4.3
Edema†	10	0.7
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain‡	36	2.9
Gastrointestinal disorders		
Diarrhea§	33	4.3
Nausea	13	0.7
Abdominal pain‖	12	1.4
Constipation	12	0.7
Skin and subcutaneous tissue disorders		
Rash¶	30	0.7
Pruritus	19	0
Infections and infestations		
Upper respiratory tract infection#	22	0
Urinary tract infection**	13	2.2
Vascular disorders		
Hemorrhage††	18	0.7
Hypertension‡‡	17	9
Metabolism and nutrition disorders		
Decreased appetite	14	1.4
Blood and lymphatic system disorders		
Anemia	14	0.7
Respiratory, thoracic, and mediastinal disorders		
Dyspnea§§	14	0
Renal and urinary disorders		
Acute kidney injury‖‖	14	0
Nervous system disorders		
Headache	13	1.4
Dizziness¶¶	12	0
Peripheral neuropathy##	11	0
Endocrine disorders		
Hypothyroidism***	12	0
Investigations		
Liver function test abnormalities†††	10	1.4

Toxicity was graded per NCI CTCAE v.4.03.[1]

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

†Edema is a composite term that includes peripheral edema, peripheral swelling, and face swelling.[1]

‡Musculoskeletal pain is a composite term that includes arthralgia, back pain, pain in extremity, myalgia, neck pain, non-cardiac chest pain, arthritis, musculoskeletal chest pain, musculoskeletal stiffness, musculoskeletal discomfort, and spinal pain.[1]

§Diarrhea is a composite term that includes diarrhea, colitis, autoimmune colitis, and enterocolitis.[1]

‖Abdominal pain is a composite term that includes abdominal pain, abdominal pain upper, abdominal pain lower, and gastrointestinal pain.[1]

¶Rash is a composite term that includes rash maculopapular, eczema, rash, dermatitis, erythema, dermatitis acneiform, rash pruritic, rash pustular, dermatitis bullous, dyshidrotic eczema, pemphigoid, rash erythematous, urticaria, nodular rash, and skin exfoliation.[1]

#Upper respiratory tract infection is a composite term that includes upper respiratory tract infection, influenza like illness, nasopharyngitis, rhinitis, sinusitis, viral rhinitis, pharyngitis, laryngitis, respiratory tract infection, influenza, viral upper respiratory tract infection, and influenza A virus test positive.[1]

**Urinary tract infection is a composite term that includes urinary tract infection, cystitis, and urosepsis.[1]

††Hemorrhage is a composite term that includes tumor hemorrhage, hematuria, epistaxis, eye hemorrhage, hemoptysis, hemorrhage intracranial, hemorrhagic diathesis, postmenopausal hemorrhage, rectal hemorrhage, skin hemorrhage, skin neoplasm bleeding, ulcer hemorrhage, vaginal hemorrhage, wound hemorrhage, and subcutaneous hematoma.[1]

‡‡Hypertension is a composite term that includes hypertension, blood pressure increased, and hypertensive crisis.[1]

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

‖‖Acute kidney injury is a composite term that includes blood creatinine increased, acute kidney injury, renal failure, renal impairment, glomerular filtration rate decreased, and nephropathy toxic.[1]

¶¶Dizziness is a composite term that includes dizziness and vertigo.[1]

##Peripheral neuropathy is a composite term that includes paresthesia, dysesthesia, hypoesthesia, peripheral motor neuropathy, burning sensation, neuralgia, and peripheral sensory neuropathy.[1]

***Hypothyroidism is a composite term that includes hypothyroidism, blood thyroid stimulating hormone increased, and immune-mediated hypothyroidism.[1]

†††Liver function test abnormalities is a composite term that includes alanine aminotransferase increased, aspartate aminotransferase increased, bilirubin conjugated increased, blood alkaline phosphatase increased, blood bilirubin increased, and gamma-glutamyl transferase increased.[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, see additional Important Safety Information throughout and in Section 5 of the accompanying full Prescribing Information.

Grade 3-4 laboratory abnormalities in Study 1620[1]

Laboratory abnormalities in ≥1% of patients	LIBTAYO (N=138) Grades 3-4, %*
Hematology	
Lymphopenia	2.9
Electrolytes	
Hyponatremia	2.9
Hypokalemia	1.5
Coagulation	
Activated partial thromboplastin time prolonged	1.9

- The most common ARs reported in at least 15% of patients were fatigue, musculoskeletal pain, diarrhea, rash, upper respiratory tract infection, pruritus, hemorrhage, and hypertension[1]
- The most common Grade 3 or 4 ARs (>2%) were hypertension, diarrhea, fatigue, musculoskeletal pain, hypokalemia, hyponatremia, pneumonia, urinary tract infection, visual impairment, and weight decreased[1]
- The most common (>2%) laboratory abnormalities worsening from baseline to Grade 3 or 4 were lymphopenia and hyponatremia[1]
- Serious ARs occurred in 34% of patients. Serious ARs that occurred in >1.5% were diarrhea (3.6%), urinary tract infection (3.6%), pneumonia (2.9%), and hemorrhage (2.2%)[1]
- Fatal ARs occurred in 4.3% of patients who received LIBTAYO, including acute kidney injury (0.7%) and cachexia worsening due to colitis (0.7%)[1]
- Permanent discontinuation of LIBTAYO due to an AR occurred in 14% of patients. ARs resulting in permanent discontinuation of LIBTAYO in at least 2 patients were diarrhea, acute kidney injury, general physical health deterioration, and hepatitis[1]
- Dosage interruptions of LIBTAYO due to an AR occurred in 40% of patients. ARs which required dosage interruptions in >2% of patients included diarrhea, musculoskeletal pain, acute kidney injury, fatigue, fall, headache, infusion-related reaction, hemorrhage, pneumonitis, upper respiratory tract infection, and urinary tract infection[1]

Toxicity graded per NCI CTCAE v.4.03.[1]

*Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter.[1]

Important Safety Information (continued)

Warnings and Precautions (continued)

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.

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® (cemiplimab-rwlc)[1]*

The safety of LIBTAYO was evaluated in 1281 patients with advanced solid malignancies[1]

Immune-mediated adverse reactions (imARs)	ARs, % (N=1281)*					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	2.6	1.6	0.6	0.3	NR	1.3	1.4	100	61
Colitis	2.0	0.9	0.8	NR	NR	0.4	1.2	100	56
Hepatitis	2.4	0.2	1.6	0.3	<0.1	1.4	0.7	100†	39
Endocrinopathies									
Adrenal insufficiency	0.5	NR	0.5	NR	NR	<0.1	<0.1	83	17
Hypophysitis‡	0.5	0.3	0.2	NR	NR	<0.1	0.2	86	14
Thyroiditis§	0.6	0.3	NR	NR	NR	0	<0.1	0	13
Hyperthyroidism	3.0	0.9	<0.1	NR	NR	0	0.5	8	56
Hypothyroidism‖	7	6	<0.1	NR	NR	0.2	0.7	1.1	6
Type 1 diabetes mellitus¶	<0.1	NR	NR	<0.1	NR	0	0.1	NR	NR
Nephritis with renal dysfunction	0.7	0.5	<0.1	NR	<0.1	0.2	0.4	100	78
Dermatologic#	1.9	0.8	0.9	NR	NR	0.2	1.3	100	71

*Important imARs listed here may not include all possible severe and fatal immune-mediated reactions.[1]
†Four 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]

NR=Not reported in the USPI. Does not necessarily mean the value is 0 and may have occurred in a small percentage of patients.

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

Important Safety Information (continued)

Warnings and Precautions (continued)

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.

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

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

Other imARs	ARs, % (N=1281)* All Grades, %
Cardiac/vascular†	<1
Nervous system‡	<1
Ocular§	<1
Gastrointestinal‖	<1
Musculoskeletal and connective tissue¶	<1
Endocrine#	<1
Hematologic/ immune**	<1

*These imARs occurred in 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 ARs.[1]
†Includes myocarditis, pericarditis, and vasculitis.[1]
‡Includes meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy.[1]
§Includes 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]
‖Includes pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, and stomatitis.[1]
¶Includes myositis/polymyositis/dermatomyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, and polymyalgia rheumatica.[1]
#Includes hypoparathyroidism.[1]
**Includes hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, and solid organ transplant rejection.[1]

Important Safety Information (continued)

Adverse Reactions

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

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

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) has straightforward dosing[1]

A fixed 350 mg dose from a single-dose vial

30 MIN

An IV infusion over 30 mins

Q3W

Every 3 weeks

Treatment should be continued until disease progression, unacceptable toxicity, or up to 24 months[1]

IV=intravenous.

Important Safety Information (continued)

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.

LIBTAYO Surround may be able to help support patients throughout their treatment journey*

LIBTAYO SURROUND® | Visit **LIBTAYOSurround.com** to learn more.

Financial support

Support that facilitates access to medication when eligible patients need assistance with out-of-pocket costs. LIBTAYO Surround will help investigate your patients' eligibility in the following programs:

- Commercial Copay Program†
- Patient Assistance Program‡

Access and reimbursement support

Support to help your patients get access to their prescribed LIBTAYO as quickly as possible, including:

- Benefits investigation
- PA and appeal assistance
- Claims assistance for billing and reimbursement
- Product support

Additional LIBTAYO Surround support

Support from our dedicated Patient Navigators, who are available to educate and assist patients once they are prescribed LIBTAYO.

Billing and coding

- NDC: 61755-008-01 or 61755-0008-0§ (350 mg/7 mL)
- J-code: J9119 Injection, cemiplimab-rwlc, 1 mg

Effective July 1, 2023, the JZ modifier is required for reporting there was no discarded drug.

For more information, call **1.877.LIBTAYO** (1.877.542.8296), select **option 1**, Monday–Friday, 8:00 AM–8:00 PM Eastern Time.

*LIBTAYO Surround provides access and reimbursement support to help your patients receive their medication as quickly as possible. Upon receipt of a LIBTAYO Surround Enrollment Form, a LIBTAYO Surround Reimbursement Specialist may be able to provide several atypes of assistance.

†Subject to annual maximum copay assistance amount of $25,000 toward out-of-pocket treatment costs for LIBTAYO, including deductibles, copays and coinsurance for LIBTAYO drug and administration charges. This program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, Veterans Affairs/Department of Defense, TRICARE, or similar federal or state programs. Not a debit card program. The program does not cover or provide support for supplies for LIBTAYO. Patients who are residents of Massachusetts or Rhode Island are not eligible for LIBTAYO administration assistance. This program only applies to patients who are at least 18 years of age, residents of the United States or its territories or possessions, are prescribed LIBTAYO (cemiplimab-rwlc) for an FDA-approved indication, and are insured by a commercial health plan that requires a copayment, coinsurance, and/or deductible amount for LIBTAYO. It is not an insurance benefit. LIBTAYO Surround reserves the right to rescind, terminate, or amend this offer, eligibility, and terms and conditions at any time without notice. Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer. This offer is not conditioned on any past, present, or future purchase, including refills. This offer is nontransferable, limited to one per person, and cannot be combined with any other offer or discount. This program is not valid where prohibited by law, taxed, or restricted. Offer has no cash value. Patients are responsible for any out-of-pocket costs for LIBTAYO that exceed the program assistance limit of $25,000 per year. Program is not valid for cash-paying customers. Additional program conditions may apply.

‡Patients who are uninsured, underinsured, or lack coverage may be eligible to receive LIBTAYO at no cost. Eligible patients will be enrolled for up to 12 months; eligible Medicare patients will be enrolled until the end of the calendar year. Patients must reapply annually. Patient eligibility criteria, including household income limits, and program conditions may apply. LIBTAYO Surround can help evaluate patients' eligibility for assistance.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

EVIDENCE THAT EMPOWERS CHANGE

Empowering decision-making in patients with advanced CSCC and advanced BCC

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

ADVANCED BCC: LIBTAYO is the **FIRST AND ONLY** treatment indicated for patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.[1]

NCCN Guidelines recommend cemiplimab-rwlc (LIBTAYO) for systemic therapy*

- **Preferred category 2A** option for patients with advanced CSCC when curative surgery and curative radiation therapy are not feasible[18]
- **Recommended category 2A** option for patients with advanced BCC who were previously treated with an HHI or for whom an HHI is not appropriate[19]

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*Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate. All recommendations are Category 2A unless otherwise specified.[18,19]

Validated in the **largest clinical trial program** for a PD-1 inhibitor in advanced CSCC and advanced BCC[1,37-45]

#1 most-prescribed IO by oncologists across both advanced CSCC and advanced BCC[2†]

>10 years of clinical treatment experience[3‡]

>33k patients treated with LIBTAYO across all indications[2†§]

†Estimate based on IQVIA medical claims data from October 2018 through December 2024 and calibrated with actual vials sold.[2]

‡FDA approved in advanced CSCC in 2018. Includes clinical trial experience and postmarketing data.[1,3]

§Since its first approval in 2018.[1]

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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, see additional Important Safety Information throughout and in Section 5 of the accompanying full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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