LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO: Approved in locally advanced BCC and over 5 years of clinical treatment experience in advanced CSCC[1-3]*

*LIBTAYO was FDA approved in advanced CSCC in September 2018.[1,4]

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]

Advanced CSCC

The #1 most-prescribed systemic therapy by oncologists for patients with advanced CSCC[1,5†]

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]

†Based on IQVIA medical claims data from October 2018 to November 2020. Claims calibrated with actual vials sold.[5]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

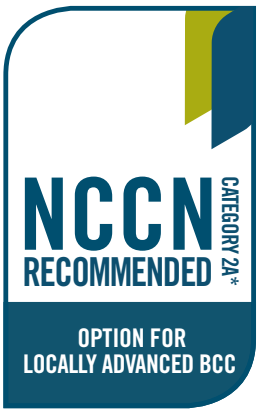
Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting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

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

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

NCCN Guidelines® for Basal Cell Skin Cancer V.2.2021 **include cemiplimab-rwlc (LIBTAYO®) as a recommended systemic therapy option for appropriate patients with locally advanced BCC[6]***

Category 2A[6]* recommended systemic therapy option



Cemiplimab-rwlc (LIBTAYO®) for locally advanced BCC†

patients previously treated with an HHI or for whom an HHI is not appropriate

Only recommended PD-1 inhibitor

*Category 2A recommendation is based upon lower-level evidence; there is uniform NCCN consensus that the intervention is appropriate. All recommendations are Category 2A unless otherwise specified.

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†Locally advanced BCC is defined as primary or recurrent local disease that is not amenable to surgery or RT.

RT=radiation therapy.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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

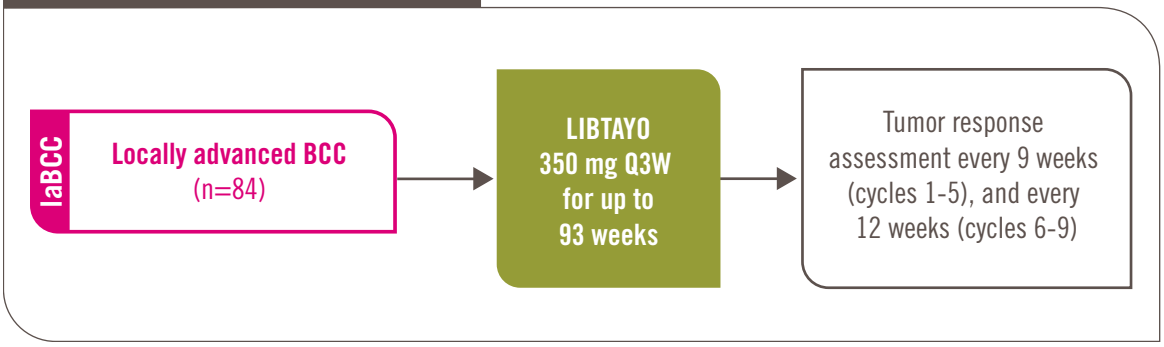
No dose reduction for LIBTAYO is recommended. In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require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

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

In patients with laBCC previously treated with an HHI,

LIBTAYO was validated in the largest prospective clinical trial for a PD-1 inhibitor

Study 1620 trial design[1]



Primary endpoint[1]

- Confirmed objective response rate (ORR) as assessed by independent central review (ICR)

Secondary endpoints included[5]

- Duration of response
- Complete response rate
- Safety and tolerability

Study 1620 was an open-label, multicenter, phase 2, nonrandomized study that included 132 patients, of which 84 patients had laBCC 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.[1,5]

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 Eastern Cooperative Oncology Group Performance Status ≥2.[1]

PD-L1=programmed death ligand 1; Q3W=every 3 weeks.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

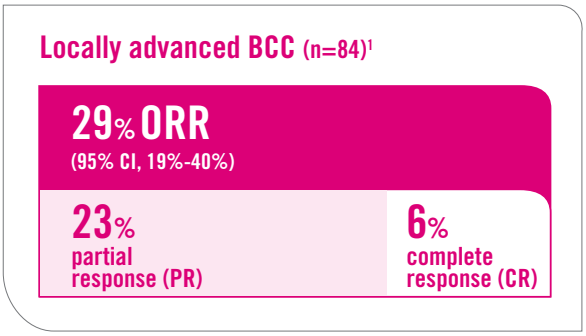
Withhold or permanently discontinue LIBTAYO depending on severity. In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less.

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,

LIBTAYO® (cemiplimab-rwlc) demonstrated clinically meaningful and durable responses[1]



- Median duration of follow-up was 15.1 months[1]

Observed duration of response[1]	Locally advanced BCC
≥6 months	79.2% of responders (19 out of 24)

- Median duration of response was not reached (range 2.1-21.4+ months)[1]
- 4.2 months median TTR (range, 2.1-13.4)[1]

No PD-L1 or TMB testing is required before starting LIBTAYO for laBCC[1,5]

In an exploratory subgroup analysis of patients with laBCC, ORR by reason for HHI discontinuation[5]:

Progression/ lack of response	Intolerance
29% (18/63)	29% (6/21)

Limitations:

- This analysis may not have had enough power for hypothesis tests

ORR is determined by the proportion of patients with best overall response of CR or PR based on independent central-reviewed 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.[5]

CR is defined as 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 (<l cm). Only includes patients with complete healing of prior cutaneous involvement; patients with laBCC in the study required biopsy to confirm CR.[5]

PR is defined as a decrease of 30% or greater 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% or greater 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.[5]

Plus sign (+) denotes ongoing at last assessment.

CI=confidence interval; DOR=duration of response; PD=progressive disease; RECIST=Response Evaluation Criteria in Solid Tumors; TMB=tumor mutational burden; TTR=time to response; WHO=World Health Organization.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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.

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

LIBTAYO demonstrated a favorable safety profile in Study 1620[1]*

Adverse reactions (ARs) in ≥10% of patients	LIBTAYO (N=132)	
	All Grades, %	Grades 3-4, %
General disorders and administration site conditions		
Fatigue[†]	49	3.8
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[‡]	33	1.5
Gastrointestinal disorders		
Diarrhea	25	0
Nausea	12	0.8
Constipation	11	0.8
Skin and subcutaneous tissue disorders		
Rash[§]	22	0.8
Pruritus	20	0
Infections and infestations		
Upper respiratory tract infection[‖]	15	0
Urinary tract infection	12	2.3
Metabolism and nutrition disorders		
Decreased appetite	14	1.5
Blood and lymphatic system disorders		
Anemia	13	0.8
Nervous system disorders		
Headache	12	1.5
Respiratory, thoracic, and mediastinal disorders		
Dyspnea[¶]	11	0
Vascular disorders		
Hypertension[#]	11	4.5

***Of the 132 patients in the safety analysis of Study 1620, 84 had laBCC.**

- Serious ARs occurred in 32% of patients. Serious ARs that occurred in >1.5% (at least 2 patients) were urinary tract infections, colitis, acute kidney injury, adrenal insufficiency, anemia, infected neoplasm, and somnolence
- Fatal ARs occurred in 1.5% of patients who received LIBTAYO, including acute kidney injury and cachexia
- Permanent discontinuation of LIBTAYO due to an AR occurred in 13% of patients
- ARs resulting in permanent discontinuation of LIBTAYO in >1.5% (at least 2 patients) were colitis and general physical health deterioration

Warnings and Precautions for LIBTAYO

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 full Prescribing Information. See link below.

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03.
[†]Fatigue is a composite term that includes fatigue, asthenia, and malaise.
[‡]Musculoskeletal pain is a composite term that includes arthralgia, back pain, myalgia, pain in extremity, musculoskeletal pain, neck pain, musculoskeletal stiffness, musculoskeletal chest pain, musculoskeletal discomfort, and spinal pain.
[§]Rash is a composite term that includes rash maculo-papular, rash, dermatitis, dermatitis acneiform, erythema, rash pruritic, dermatitis bullous, dyshidrotic eczema, pemphigoid, rash erythematous, and urticaria.
[‖]Upper respiratory tract infection is a composite term that includes upper respiratory tract infection, nasopharyngitis, rhinitis, sinusitis, pharyngitis, respiratory tract infection, and viral upper respiratory tract infection.
[¶]Dyspnea is a composite term that includes dyspnea and dyspnea exertional.
[#]Hypertension is a composite term that includes hypertension and hypertensive crisis.
HSCT=hematopoietic stem cell transplantation.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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

Laboratory abnormalities in ≥1% of patients	LIBTAYO (N=132) Grades 3-4, %†
Electrolytes	
Hyponatremia	3.1
Hypokalemia	1.5
Coagulation	
Activated partial thromboplastin time prolonged	2.3
Hematology	
Lymphocyte count decreased	2.3

***Of the 132 patients in the safety analysis of Study 1620, 84 patients had laBCC.**

- Dosage delays of LIBTAYO® (cemiplimab-rwlc) due to an AR occurred in 34% of patients. ARs which required dosage delay in >2% of patients (at least 3 patients) included blood creatinine increased, diarrhea, colitis, fatigue, headache, pneumonitis, and urinary tract infection
- The most common ARs reported in at least 15% of patients were fatigue, musculoskeletal pain, diarrhea, rash, pruritus, and upper respiratory tract infection
- The most common Grade 3 or 4 ARs (>2%) were hypertension, colitis, fatigue, urinary tract infection, pneumonia, increased blood pressure, hypokalemia and visual impairment
- The most common (>3%) laboratory abnormalities worsening from baseline to Grade 3 or 4 was hyponatremia

Toxicity graded per NCI CTCAE v.4.03.
†Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

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 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.

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%).

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

With over 5 years of clinical treatment experience, LIBTAYO is the first PD-1 inhibitor approved for advanced CSCC[1-3*]

*LIBTAYO was FDA approved in advanced CSCC in September 2018.[1,4]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Squamous Cell Skin Cancer V.1.2021 recommend cemiplimab-rwlc (LIBTAYO®) as a preferred systemic therapy option for appropriate patients with advanced CSCC[7†]

Category 2A† preferred recommendation[7]

NCCN CATEGORY 2A† PREFERRED
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**

†Category 2A recommendation is based upon lower-level evidence; there is uniform NCCN consensus that the intervention is appropriate. All recommendations are Category 2A unless otherwise specified.

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‡For patients who have complicated cases of locally advanced disease in which curative surgery and curative radiation therapy are not feasible. Assessment feasibility of radiation therapy should be made by a radiation oncologist.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

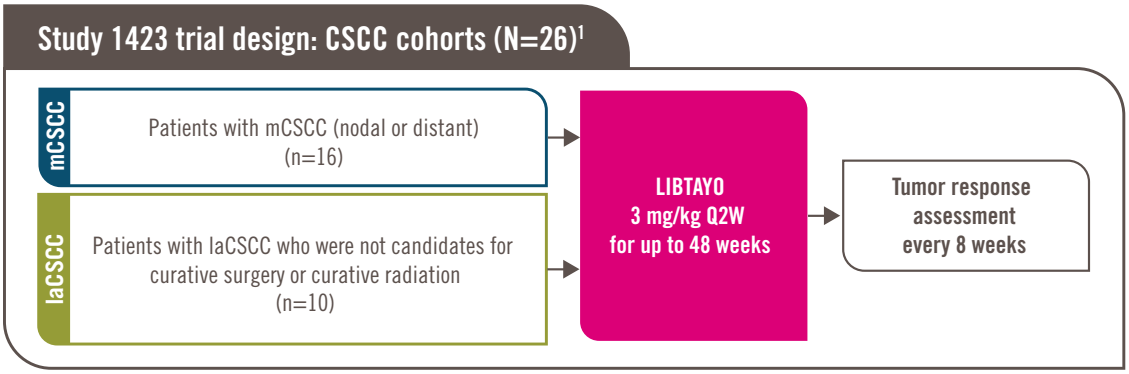
Immune-mediated colitis (continued): Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBTAYO in 1.5% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients. Of the 12 patients in whom LIBTAYO was withheld, 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.

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.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) was validated in the largest prospective clinical trial program for advanced CSCC[1,8-16]



Primary endpoint[1,17]:

- To characterize safety and tolerability of LIBTAYO

Secondary endpoints included[1,17]:

- Antitumor activity

Study 1423 was an open-label, multicenter, nonrandomized, multicohort study that included 26 patients with mCSCC (n=16) or laCSCC (n=10) who were not candidates for curative surgery or curative radiation. Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 48 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]

Study 1423 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 or unacceptable toxicity.[1]

Efficacy endpoints in patients with advanced CSCC in Study 1423[1,5]*:

- **ORR was 50%** (13 out of 26 patients [95% CI, 30%-70%]); all responses were PRs
- Median time to response was **1.9 months** (range, 1.7-7.3 months)
- **85% of responders** (11 out of 13) reached a DOR ≥6 months

In this trial, DOR range was 1.0 to 20.3 months

*Data cutoff date was June 30, 2018. Median duration of follow-up was 13.3 months.[1,5]
ECOG=Eastern Cooperative Oncology Group; PS=performance status; Q2W=every 2 weeks.

Important Safety Information (continued)

Warnings and Precautions (continued)

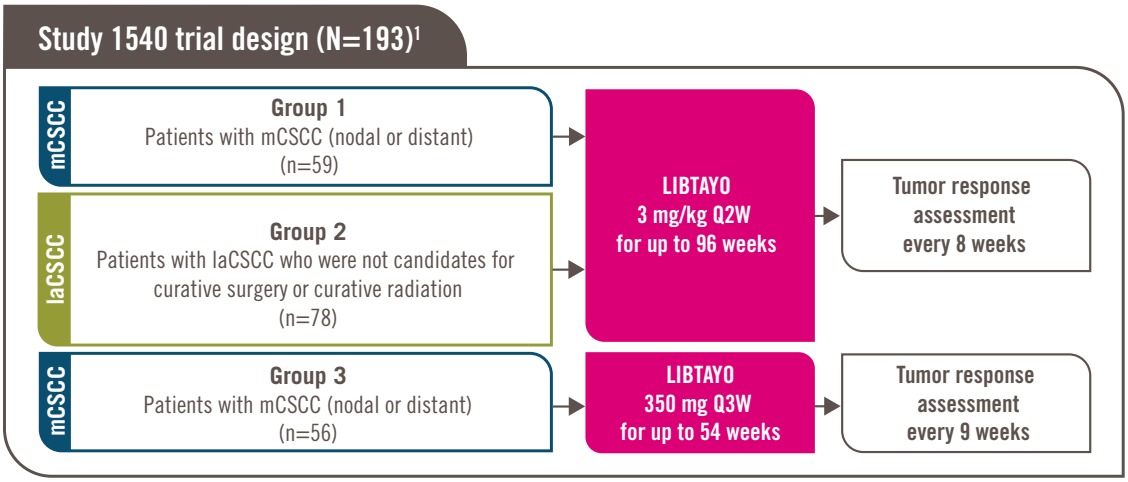
Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued):

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

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

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



Primary endpoint[1,5]:

- Confirmed ORR by ICR

Secondary endpoints included[1,5]:

- 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 or unacceptable toxicity.[1]

In Study 1540, 66% of patients received LIBTAYO as first-line systemic therapy, 90% 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.[1,3,5]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued):

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

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

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

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

LIBTAYO® (cemiplimab-rwlc)
Injection 350 mg

Proven efficacy in patients with advanced CSCC who received LIBTAYO® (cemiplimab-rwlc) in Study 1540[1,5]

For patients with mCSCC or laCSCC who are not candidates for curative surgery or curative radiation and who received LIBTAYO 3 mg/kg Q2W in Study 1540[1]*:

46% ORR (63 out of 137 patients; 95% CI, 37%-55%)[1,5†]

31% PR (43 out of 137 patients)[1,5]

15% CR (20 out of 137 patients)[1,5]

79% of responders (50 out of 63) reached a DOR ≥6 months, and

54% of responders (34 out of 63) reached a DOR ≥12 months[1,5†]

Median TTR was rapid at **1.9 months** (range, 1.7-9.1 months) based on an open-label, single-arm trial that did not include comparisons to other treatments[1‡]

- In an additional cohort in Study 1540 of 56 patients with mCSCC who received LIBTAYO 350 mg Q3W,* ORR was 41% (95% CI, 28%-55%); 65% of responders reached a DOR ≥6 months[1†]
- In this trial, median DOR was not reached (range, 1.9-24.2+ months)[5†]
- The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity[1]

*Data cutoff was September/October 2018.[5]
†Median duration of follow-up was 11.1 months and 8.0 months in patients who received LIBTAYO 3 mg/kg Q2W and LIBTAYO 350 mg Q3W in Study 1540, respectively.[1]
‡First assessment was performed at 8 weeks.[5]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

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

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

Long-term follow-up data for LIBTAYO[3,5]*

Response rates in patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation (N=137), based on efficacy results for Study 1540: 3 mg/kg every 2 weeks[1]

The following data represents a 3-year follow-up for Group 1 and a 2-year follow-up for Group 2 and Group 3.* Follow-ups for each group are based on time from primary analysis.[3]

	mCSCC 3 mg/kg Q2W	laCSCC 3 mg/kg Q2W	mCSCC 350 mg Q3W	Combined advanced CSCC
Tumor response assessment by ICR	Group 1 (n=59)	Group 2 (n=78)	Group 3 (n=56)	Groups 1, 2, & 3 (N=193)
Median duration of follow-up, months (range)	18.5 (1.1-41.0)	15.5 (0.8-43.2)	17.3 (0.6-38.5)	**15.7 (0.6-43.2)**
ORR, % (95% CI)	50.8% (37.5%-64.1%)	44.9% (33.6%-56.6%)	46.4% (33.0%-60.3%)	**47.2% (39.9%-54.4%)**
CR, n (%)	12 (20.3%)	10 (12.8%)	11 (19.6%)	**33 (17.1%)**
PR, n (%)	18 (30.5%)	25 (32.1%)	15 (26.8%)	**58 (30.1%)**
Time to response (TTR) and observed duration of response (DOR)				
Median observed time to response, months (IQR)†	1.9 (1.8-2.0)	2.1 (1.9-3.8)	2.1 (2.1-4.2)	**2.1 (1.9-3.7)**
Median DOR, months (95% CI)†	NR (20.7-NE)	NR (18.4-NE)	NR (NE-NE)	**NR (31.1-NE)**
Patients with DOR ≥6 months, n (%)‡	28 (93.3%)	30 (85.7%)	25 (96.2%)	**83 (91.2%)**
Patients with DOR ≥12 months, n (%)‡	23 (76.7%)	22 (62.9%)	20 (76.9%)	**65 (71.4%)**
Patients with DOR ≥24 months, n (%)‡	18 (60.0%)	13 (37.1%)	14 (53.8%)	**45 (49.5%)**

*For these longer-term data, the predetermined data cutoff date was October 11, 2020.[3]

†Based on number of patients with confirmed CR or PR.[3]

‡Percentages are based on number of patients with confirmed CR or PR. The numerator includes the number of patients whose observed duration of response reached at least the specified time. Patients who did not have the opportunity to reach the specified timepoint were included in the denominator only. Because responses for some patients are ongoing, the percentages at the specified timepoints may increase as data mature.[5]

Adapted with permission from Rischin et al, 2021.[3]

CR=complete response; IQR=interquartile range; NE=not evaluable; NR=not reached; PR=partial response.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

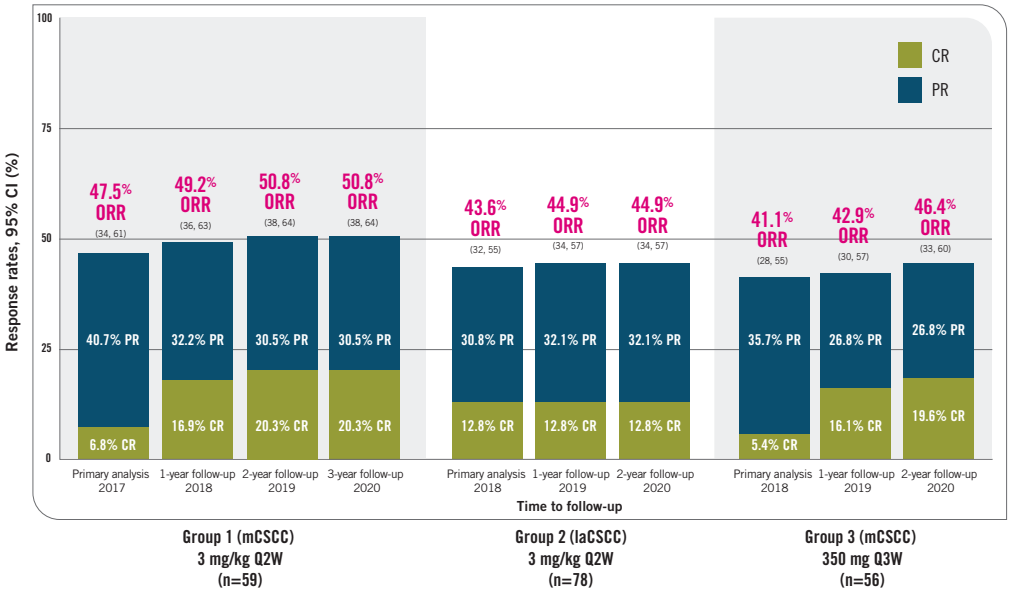
- **Thyroiditis:** Thyroiditis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including Grade 2 (0.2%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 patient. Systemic corticosteroids were not required in any patient with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

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor response assessment in patients by ICR across analyses from Study 1540[1,3,5,18]

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



Response rates are based on analysis by independent central review of Study 1540 at time of data cutoff.

Over 6000 patients with advanced CSCC have been prescribed LIBTAYO® (cemiplimab-rwlc) by oncologists since approval in 2018, more than any other systemic therapy[5]*

*Based on IQVIA medical claims data from October 2018 to November 2020. Claims calibrated with actual vials sold.[5]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 0.5% of patients due to hyperthyroidism. Systemic corticosteroids were required in 3.8% (1/26) of patients. Hyperthyroidism resolved in 50% of 26 patients. Of the 4 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism
- **Hypothyroidism:** Hypothyroidism occurred in 7% (60/810) of patients receiving LIBTAYO, including Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. Hypothyroidism led to withholding of LIBTAYO in 1.1% of patients. Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 8.3% of the 60 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement; 1 required ongoing hormone replacement therapy

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

LIBTAYO demonstrated a favorable safety profile in patients with advanced CSCC in clinical studies[1]*

Adverse reactions in ≥10% of patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation, and who received LIBTAYO in Study 1423 and Study 1540

Adverse reactions	Combined advanced CSCC (N=219)	
	All Grades, %	Grades 3-4, %
General disorders and administration site		
Fatigue†	34	3
Skin and subcutaneous tissue		
Rash‡	31	1
Pruritus§	18	0
Gastrointestinal		
Diarrhea‖	25	0.5
Nausea	21	0
Constipation	13	0.5
Vomiting	10	0.5
Musculoskeletal and connective tissue		
Musculoskeletal pain¶	24	3
Arthralgia	11	1
Respiratory		
Cough#	14	0
Hematology		
Anemia	11	4
Endocrine		
Hypothyroidism	10	0
Metabolism and nutrition		
Decreased appetite	10	0

Warnings and Precautions for LIBTAYO

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 full Prescribing Information. See link below.

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

*Safety profile shown is representative of the analysis within the USPI.

†Fatigue is a composite term that includes fatigue and asthenia.

‡Rash is a composite term that includes rash, rash maculopapular, erythema, dermatitis, dermatitis bullous, rash generalized, pemphigoid, rash erythematous, rash macular, rash pruritic, drug eruption, psoriasis, and skin reaction.

§Pruritus is a composite term that includes pruritus and pruritus allergic.

‖Diarrhea is a composite term that includes diarrhea and colitis.

¶Musculoskeletal pain is a composite term that includes back pain, pain in extremity, myalgia, musculoskeletal pain, and neck pain.

#Cough is a composite term that includes cough and upper airway cough syndrome.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Grade 3 or 4 laboratory abnormalities in patients with advanced CSCC in clinical studies[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® (cemiplimab-rwlc) in Study 1423 and Study 1540

	Combined advanced CSCC (N=219)
Laboratory abnormalities	**Grades 3-4, %†**
Chemistry	
Increased aspartate aminotransferase	2
Increased INR	2
Hematology	
Lymphopenia	9
Anemia	5
Electrolytes	
Hyponatremia	5
Hypophosphatemia	4
Hypercalcemia	2

- The most common (≥20%) adverse reactions were fatigue, rash, diarrhea, musculoskeletal pain, and nausea
- The most common Grade 3-4 ARs (≥2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia. The most common (≥4%) Grade 3 or 4 laboratory abnormalities worsening from baseline were lymphopenia, anemia, hyponatremia, and hypophosphatemia
- LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients
- ARs resulting in permanent discontinuation were pneumonitis, cough, pneumonia, encephalitis, aseptic meningitis, hepatitis, arthralgia, muscular weakness, neck pain, soft tissue necrosis, complex regional pain syndrome, lethargy, psoriasis, rash maculopapular, proctitis, and confusional state
- Serious ARs occurred in 35% of patients
- Serious ARs that occurred in at least 2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia

*Safety profile shown is representative of the analysis within the USPI.
†Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter. Toxicity graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03.

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% (1/810) 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

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.

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

Long-term follow-up data for Study 1540: Safety profile[3]

Adverse reactions 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

	Combined advanced CSCC (N=193)	
Adverse reactions	**All Grades, %**	**Grade ≥3, %**
Any	**99.5**	**49.2**
Led to discontinuation	**10.4**	**7.3**
Most common*		
Fatigue	34.7	2.6
Diarrhea	27.5	1.0
Nausea	23.8	0
Pruritus	21.2	0
Cough	16.6	0
Rash	16.6	0.5
Arthralgia	14.5	0.5
Constipation	14.5	0.5
Vomiting	13.0	0.5
Actinic keratosis	11.9	0
Maculopapular rash	11.9	0.5
Anemia	11.4	4.1
Hypothyroidism	11.4	0
Headache	10.9	0
Upper respiratory tract infection	10.9	0

- Grade ≥3 adverse reactions occurred in 95 patients (49.2%). The most common Grade ≥3 adverse reactions were hypertension (n=9, 4.7%), anemia, cellulitis, and pneumonia (all n=8, 4.1%)

*Adverse reactions reported in ≥10% of patients, ordered by frequency of any grade.

Adapted with permission from Rischin et al, 2021.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated nephritis with renal dysfunction (continued): Of the 3 patients in whom LIBTAYO was withheld, 2 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence. Withhold LIBTAYO for Grade 2 or 3 increased blood creatinine, and permanently discontinue for Grade 4 increased blood creatinine. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

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

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 810 patients with advanced solid malignancies

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

*Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated reactions.
[†]3 patients required additional immunosuppression mycophenolate.
[‡]Can cause hypopituitarism.
[§]Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported.
[‖]Majority of patients required long-term thyroid hormone replacement.
[¶]Can present with diabetic ketoacidosis.
[#]Exfoliative dermatitis, including SJS, TEN, and DRESS, has occurred with PD-1/PD-L1–blocking antibodies.
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 nectolysis.

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 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.

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

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

Other immune-mediated adverse reactions[1]	Adverse reactions, % (N=810)*
	All Grades, %
Cardiac/vascular†	<1
Nervous system‡	<1
Ocular§	<1
Gastrointestinal‖	<1
Musculoskeletal and connective tissue¶	<1
Endocrine#	<1
Hematologic/ immune**	<1

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

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions (continued):

- **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

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

An IV infusion over 30 minutes

Every 3 weeks

Treatment should be continued until disease progression or unacceptable toxicity

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
- **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.

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

Important Safety Information (continued)

Warnings and Precautions (continued)

Complications of allogeneic HSCT (continued)

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 metastatic cutaneous 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.

References:

1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Updated January 26, 2021. Accessed July 12, 2021. **3.** Rischin D, Khushalani NI, Schmults CD, et al. Phase 2 study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC): follow-up at 43 months. Poster presented at: European Association of Dermato Oncology Congress 2021 Virtual Scientific Meeting. 15-17 April 2021. **4.** Drugs@FDA: FDA-approved drugs. US Food and Drug Administration website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761097. Updated June 25, 2020. Accessed January 19, 2021. **5.** Data on file. Regeneron Pharmaceuticals, Inc. **6.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Basal Cell Skin Cancer V.2.2021*. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed July 12, 2021. To view the most recent and complete version of the guidelines, go online to NCCN.org. **7.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Squamous Cell Skin Cancer V.1.2021.* © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed July 12, 2021. To view the most recent and complete version of the guidelines, go online to NCCN.org. **8.** Keytruda [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2020. **9.** Foote MC, McGrath M, Guminski A, et al. Phase II study of single-agent panitumumab in patients with incurable cutaneous squamous cell carcinoma. *Ann Oncol.* 2014;25(10):2047-2052. **10.** William WN Jr, Feng L, Ferrarotto R, et al. Gefitinib for patients with incurable cutaneous squamous cell carcinoma: a single-arm phase II clinical trial. *J Am Acad Dermatol.* 2017;77(6):1110-1113.e2. **11.** Heath CH, Deep NL, Carroll L, et al. Phase 1 study of erlotinib plus radiation therapy in patients with advanced cutaneous squamous cell carcinoma. *Int J Radiat Oncol Biol Phys.* 2013;85(5):1275-1281. **12.** Jenni D, Karpova MB, Mühleisen B, et al. A prospective clinical trial to assess lapatinib effects on cutaneous squamous cell carcinoma and actinic keratosis. *ESMO Open.* 2016;1(1):e000003:1-7. **13.** Lewis CM, Glisson BS, Feng L, et al. A phase II study of gefitinib for aggressive cutaneous squamous cell carcinoma of the head and neck. *Clin Cancer Res.* 2012;18(5):1435-1446. **14.** Sadek H, Azli N, Wendling JL, et al. Treatment of advanced squamous cell carcinoma of the skin with cisplatin, 5-fluorouracil, and bleomycin. *Cancer.* 1990;66(8):1692-1696. **15.** Shin DM, Glisson BS, Khuri FR, et al. Phase II and biologic study of interferon alfa, retinoic acid, and cisplatin in advanced squamous skin cancer. *J Clin Oncol.* 2002;20(2):364-370. **16.** Maubec E, Petrow P, Scheer-Senyarich I, et al. Phase II study of cetuximab as first-line single-drug therapy in patients with unresectable squamous cell carcinoma of the skin. *J Clin Oncol.* 2011;29(25):3419-3426. **17.** Migden MR, Rischin D, Schmults CD, et al. PD-1 blockade with cemiplimab in advanced cutaneous squamous-cell carcinoma. *N Engl J Med.* 2018;379(4):341-351. **18.** Rischin D, Khushalani NI, Schmults CD, et al. Phase 2 study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC): longer follow-up. Poster presented at: American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program; May 29-31, 2020. **19.** Rischin D, Lim A, Schmults C et al. Phase 2 study of 2 dosing regimens of cemiplimab, a human monoclonal anti-PD-1, in metastatic cutaneous squamous cell carcinoma (mCSCC). Poster presented at: 2020 Maui Dermatology Conference; January 25-29, 2019.

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

Locally advanced BCC

Advanced CSCC

Immune-mediated adverse reactions

Dosing and patient support

LIBTAYO: Approved in locally advanced BCC and over 5 years of clinical treatment experience in advanced CSCC[1-3]*

*LIBTAYO was FDA approved in advanced CSCC in September 2018.[1,4]

Locally Advanced BCC

- LIBTAYO is the **FIRST AND ONLY** treatment indicated for patients with locally advanced BCC previously treated with an HHI or for whom an HHI is not appropriate[1]

Advanced CSCC

- LIBTAYO is indicated for the treatment of patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

LIBTAYO SURROUND®

LIBTAYO Surround helps eligible patients access LIBTAYO and navigate the health insurance process.

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

†Based on IQVIA medical claims data from October 2018 to November 2020. Claims calibrated with actual vials sold.[5]

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 full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

REGENERON | SANOFI GENZYME