LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO offers over 4 years of clinical treatment experience in patients with advanced CSCC[1-3]*

*LIBTAYO was FDA approved in September 2018.[1,4]
CSCC=cutaneous squamous cell carcinoma.

LIBTAYO is a programmed death receptor-1 (PD-1)–blocking antibody 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]

#1 LIBTAYO IS THE #1 MOST-PRESCRIBED SYSTEMIC THERAPY BY ONCOLOGISTS FOR PATIENTS WITH ADVANCED CSCC[1,5†]

†Based on IQVIA medical claims data from October 2018 to June 2020. Claims calibrated with actual vials sold.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1/PD-L1 blocking antibodies. The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Study designs for Study 1423 and Study 1540

The efficacy of LIBTAYO in 219 patients with metastatic cutaneous squamous cell carcinoma (mCSCC) (nodal or distant) or locally advanced CSCC (laCSCC) who were not candidates for curative surgery or curative radiation was evaluated in 2 open-label, multicenter, nonrandomized, multicohort studies: Study 1423 and Study 1540. Both studies 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]

Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 48 weeks in Study 1423 or up to 96 weeks in Study 1540. An additional cohort of patients in Study 1540 received LIBTAYO 350 mg every 3 weeks for up to 54 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment. Tumor response assessments were performed every 8 or 9 weeks. The major efficacy outcome measures were confirmed objective response rate (ORR), defined as complete response (CR) plus partial response (PR) as assessed by independent central review (ICR), and ICR-assessed duration of response (DOR). For patients with mCSCC without externally visible target lesions, ORR was determined by Response Evaluation Criteria in Solid Tumors (RECIST 1.1). For patients with externally visible target lesions (laCSCC and mCSCC), ORR was determined by a composite endpoint that integrated ICR assessments of radiologic data (RECIST 1.1) and digital medical photography (WHO Criteria).[1]

The data cutoffs for Study 1423 and Study 1540 in the USPI are June 2018 and September/October 2018, respectively.[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]

Important Safety Information (continued)

Warnings and Precautions (continued)

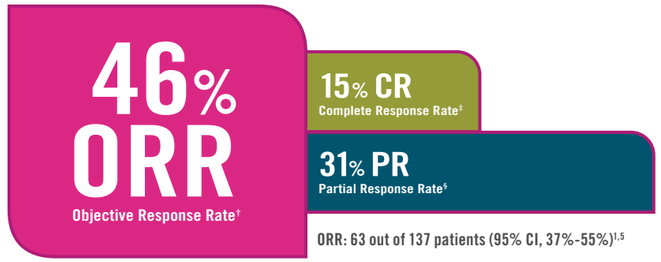
Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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 click here for full Prescribing Information.

Proven efficacy in patients with advanced CSCC[1,5*]

For patients with mCSCC or laCSCC who received LIBTAYO 3 mg/kg Q2W in Study 1540[1,5*]:



- **79% of responders** (50 out of 63) reached a DOR ≥6 months[1,5†]
- **54% of responders** (34 out of 63) reached a DOR ≥12 months[1,5†]

In an additional cohort in Study 1540 of 56 patients with mCSCC who received LIBTAYO 350 mg Q3W[1*]:

- ORR was 41% (23 out of 56 patients [95% CI, 28%-55%])[1†]
- 65% of responders (15 out of 23) reached a DOR ≥6 months

In this trial, median DOR was not reached (range, 1.9-24.2+ months).[5†]

*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] See additional study design details on the left side of this page.

‡Complete response (CR) is defined as 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.[1,5]

§Partial response (PR) is 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 progressive disease, 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.[1]

ECOG=Eastern Cooperative Oncology Group; PD-L1=programmed death ligand 1; PS=performance status; Q2W=every 2 weeks; Q3W=every 3 weeks; WHO=World Health Organization.

Efficacy endpoints in patients with advanced CSCC in Study 1423[1‖]:

- **ORR was 50%** (13 out of 26 patients [95% CI, 30%-70%]); all responses were PRs
- Median time to response (TTR) 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.[5]

‖Data cutoff date was June 30, 2018. Median duration of follow-up was 13.3 months.[1,5]

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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[1]

	Combined advanced CSCC (N=219)	
Adverse reactions	**All grades, %**	**Grade 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

*Safety profile shown is representative of the analysis within the USPI.
[†]Fatigue is a composite term that includes fatigue and asthenia.[1]
[‡]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.[1]
[§]Pruritus is a composite term that includes pruritus and pruritus allergic.[1]
[‖]Diarrhea is a composite term that includes diarrhea and colitis.[1]
[¶]Musculoskeletal pain is a composite term that includes back pain, pain in extremity, myalgia, musculoskeletal pain, and neck pain.[1]
[#]Cough is a composite term that includes cough and upper airway cough syndrome.[1]

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

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 in Study 1423 and Study 1540[1]

	Combined advanced CSCC (N=219)
Laboratory abnormalities	**Grade 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 grade 3-4 adverse reactions (≥2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia[1]
- LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients[1]
- Adverse reactions 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[1]
- Serious adverse reactions occurred in 35% of patients[1]
- Serious adverse reactions that occurred in at least 2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia[1]

**Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter.[1]
Toxicity graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03.[1]
HSCT=hematopoietic stem cell transplantation; INR=international normalized ratio.

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. See link on the left side of this page.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 57-year-old male with locally advanced CSCC[5]

Invasive disease and unlikely to respond to radiotherapy or surgery based on clinical judgment

Medical and treatment history

- Patient history indicated that the primary site of the CSCC lesion was the right forehead
- Tumor staging at initial diagnosis was TX/N1/M0
- Poorly differentiated histology

Patient underwent surgical intervention and chemotherapy with concurrent radiation over the course of 4 months

- Surgical excision
- Carboplatin/paclitaxel and concurrent definitive radiotherapy for 1.5 months

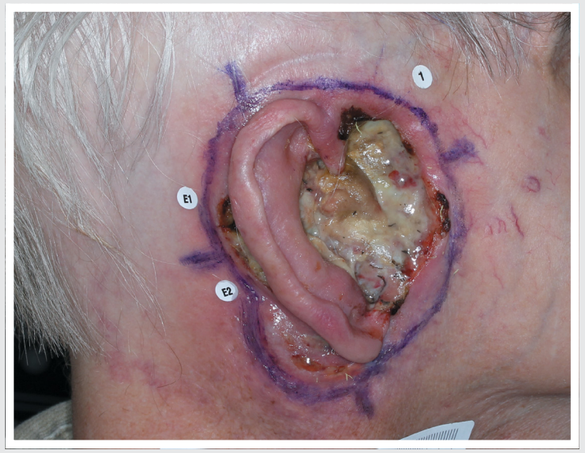
Patient experienced recurrence/relapse.

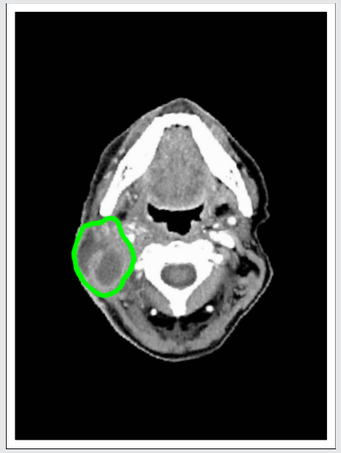
Patient complained of ongoing grade 2 pain of the right ear, with grade 1 associated hearing impairment.

Presentation at screening

- Screening -

Auricular lesion[5]





Actual clinical trial patient.

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. 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.

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 3.7% (22/591) of patients receiving LIBTAYO, including fatal (0.3%), Grade 4 (0.3%), Grade 3 (1.0%), and Grade 2 (1.9%). Pneumonitis led to permanent discontinuation in 1.9% of patients and withholding of LIBTAYO in 1.9% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 59% of the 22 patients. Of the 11 patients in whom LIBTAYO was withheld, 7 reinitiated after symptom improvement; of these 1/7 (14%) 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 57-year-old male with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

Patient was a candidate for LIBTAYO due to the following reasons[5]:

- Locally advanced CSCC
- CSCC with significant local invasion that precluded complete resection
- Judgment of the radiation oncologist was that the tumor would be unlikely to respond to radiotherapy
- Tumor stage at clinical trial screening was T2/N0/M0 (single lesion, 86.5 mm longest at baseline)
- Well-differentiated histology at clinical trial screening

Patient received LIBTAYO 3 mg/kg intravenously every 2 weeks in a clinical trial.[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]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated colitis: LIBTAYO can cause immune-mediated colitis. The primary component of immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1 blocking antibodies. In cases of corticosteroid-refractory immune-mediated colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 1.2% (7/591) of patients receiving LIBTAYO, including Grade 3 (0.3%) and Grade 2 (0.7%). Colitis led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 0.7% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 71% of the 7 patients. Of the 4 patients in whom LIBTAYO was withheld, none reinitiated LIBTAYO. 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 1.9% (11/591) of patients receiving LIBTAYO, including fatal (0.2%), Grade 4 (0.2%), and Grade 3 (1.5%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.8% of patients and withholding of LIBTAYO in 0.8% of patients. Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 9% (1/11) of these patients. Hepatitis resolved in 64% of the 11 patients. Of the 5 patients in whom LIBTAYO was withheld, none reinitiated LIBTAYO.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

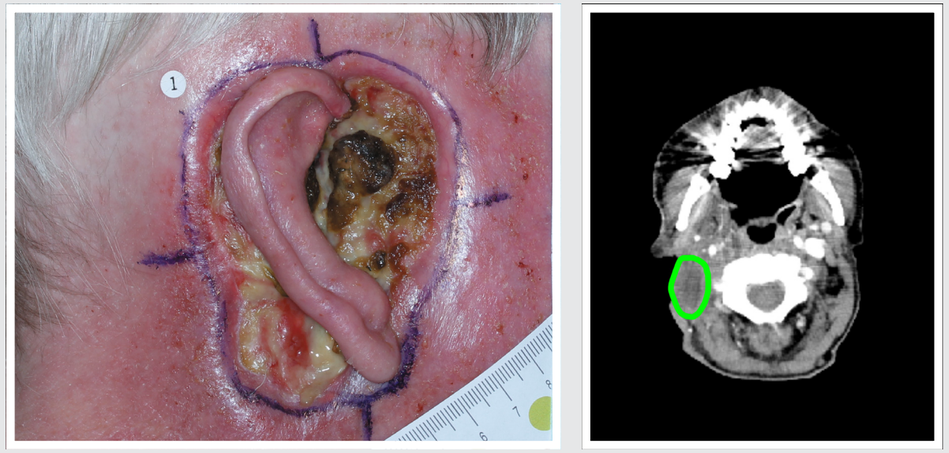
Tumor reduction in a clinical trial patient with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

This is an example from the 31% of patients who had a PR in the combined analysis of patients who received LIBTAYO 3 mg/kg Q2W in Study 1540.[1] Individual patient responses may vary.

By the first assessment, at week 8, target lesion reduction from baseline of 7.5% was observed.[5]

- After 8 weeks -

Auricular lesion[5]



Actual clinical trial patient.

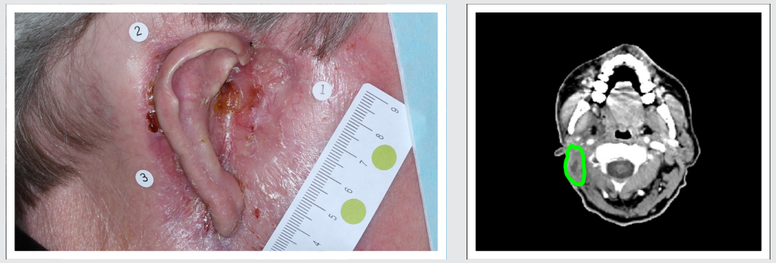
LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor reduction with LIBTAYO[5]

By week 24, target lesion reduction from baseline of 47.3% was observed.[5]

- After 24 weeks -

Auricular lesion[5]

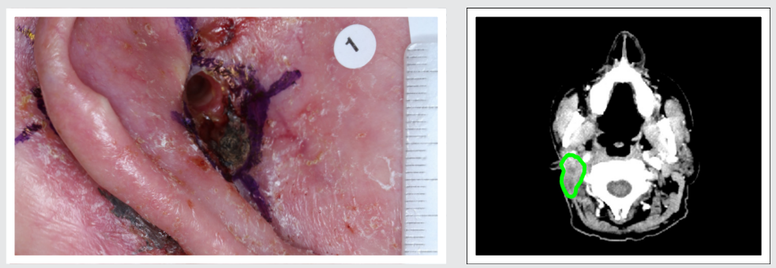


Actual clinical trial patient.

By week 32, target lesion reduction from baseline of 83.2% was observed.[5]

- After 32 weeks -

Auricular lesion[5]



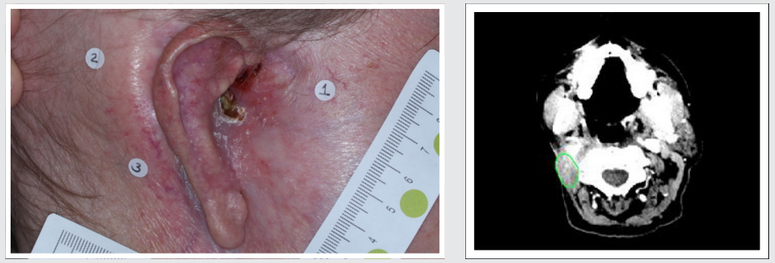
Actual clinical trial patient.

Individual patient responses may vary.

By week 88, target lesion reduction from baseline of 96.5% was observed.[5]

- After 88 weeks -

Auricular lesion[5]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff of October 2018)[5]

- Best overall response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percentage change in target lesion(s): –96.5% per WHO Criteria
- TTR: 24 weeks (5.5 months)
- DOR: 18.7 months+

Individual patient responses may vary.

LIBTAYO: A breakthrough for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

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

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated hepatitis (continued):

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

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 70-year-old male with locally advanced CSCC[5]

Invasive disease and radiotherapy contraindicated

Medical and treatment history

- Patient history indicated that the primary site of the CSCC lesion was the scalp
- Tumor staging at initial diagnosis was T4/N2B/M0
- Moderately differentiated histology
- Relevant comorbidities (not comprehensive) included diabetes mellitus

Patient underwent a series of surgical interventions and radiotherapy over the course of 4 years

- Resection of the right parotid gland
- Definitive radiotherapy to the right preauricular area
- Incisional biopsy of the skin

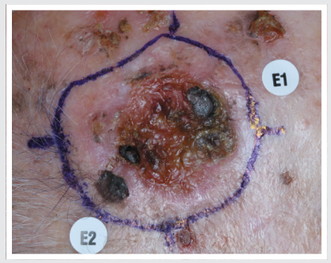
Patient experienced recurrence/relapse.

Patient complained of ongoing grade 2 pain at the right preauricular area.

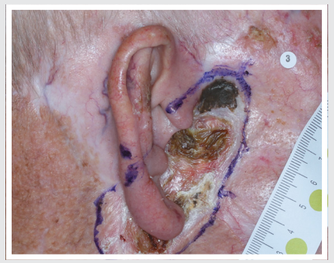
Presentation at screening

- Screening -

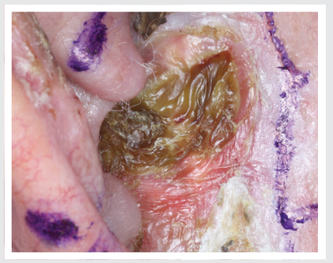
Cranial lesion[5]



Auricular lesion[5]



Auricular lesion (enlarged view)[5]



Actual clinical trial patient.

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: Withhold LIBTAYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBTAYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times ULN or if total bilirubin increases to more than 3 times ULN. If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue LIBTAYO based on recommendations for hepatitis with no liver involvement.

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

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

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Case discussion: 70-year-old male with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

Patient was a candidate for LIBTAYO due to the following reasons[5]:

- Locally advanced CSCC
- CSCC with significant local invasion that precluded complete resection
- Individualized benefit-risk assessment was performed by a multidisciplinary team who deemed that radiotherapy was contraindicated
- Tumor stage at clinical trial screening was T3/N0/M0 (4 lesions, largest at baseline was 93 mm in diameter)
- Moderately differentiated histology at clinical trial screening

Patient received LIBTAYO 3 mg/kg intravenously every 2 weeks in a clinical trial.[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]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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

- **Adrenal insufficiency:** LIBTAYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBTAYO depending on severity. Adrenal insufficiency occurred in 0.5% (3/591) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.3%). No patient discontinued or withheld LIBTAYO due to adrenal insufficiency.
- **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 0.2% (1/591) of patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis.
- **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 click here for full Prescribing Information.

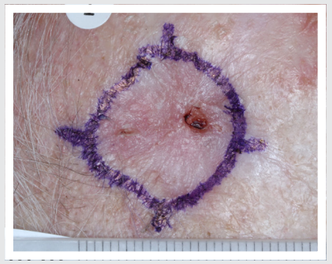
Tumor reduction in a clinical trial patient with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

This is an example from the 31% of patients who had a PR in the combined analysis of patients who received LIBTAYO 3 mg/kg Q2W in Study 1540.[1] Individual patient responses may vary.

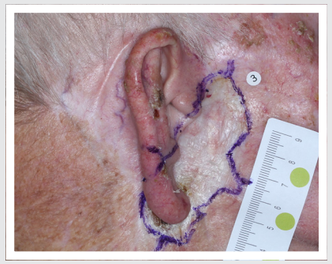
By week 16, target lesion reduction from baseline of 66.4% was observed.[5]

- After 16 weeks -

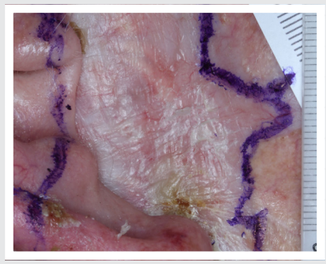
Cranial lesion[5]



Auricular lesion[5]



Auricular lesion (enlarged view)[5]



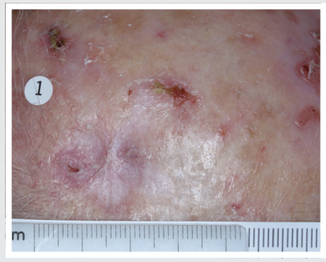
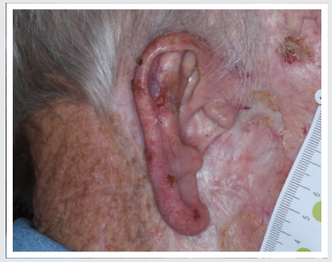
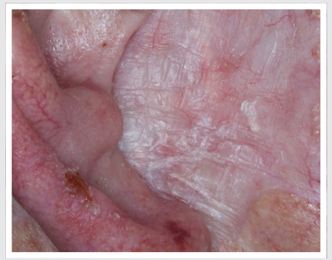
Actual clinical trial patient.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor reduction with LIBTAYO[5]

By week 24, target lesion reduction from baseline of 87.8% was observed.[5]

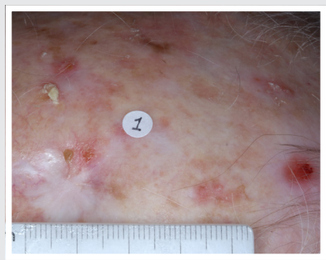
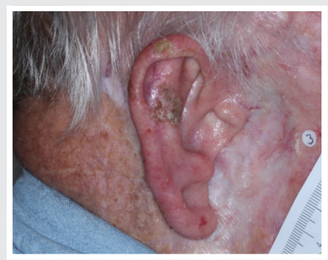
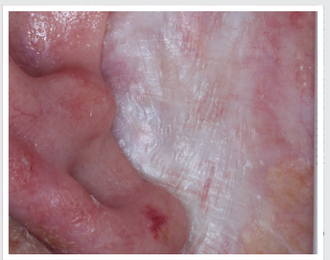
- After 24 weeks -

Cranial lesion[5]	Auricular lesion[5]	Auricular lesion (enlarged view)[5]
		

Actual clinical trial patient.

By week 96, target lesion reduction from baseline of 99.6% was observed.[5]

- After 96 weeks -

Cranial lesion[5]	Auricular lesion[5]	Auricular lesion (enlarged view)[5]
		

Actual clinical trial patient.

Individual patient responses may vary.

Clinical outcomes (as of data cutoff October 2018)[5]

- Best overall response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percentage change in target lesion(s): –99.6% per WHO Criteria
- TTR: 16 weeks (3.7 months)
- DOR: 21.2 months+

Individual patient responses may vary.

LIBTAYO: A breakthrough for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

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

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Thyroiditis:** A single case of Grade 1 thyroiditis was observed in 591 patients receiving LIBTAYO in clinical trials.
- **Hyperthyroidism:** Hyperthyroidism occurred in 1.9% (11/591) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.5%). No patient discontinued treatment and LIBTAYO was withheld in 0.3% of patients due to hyperthyroidism. Systemic corticosteroids were required in 9% (1/11) of patients. Hyperthyroidism resolved in 46% of 11 patients.
- **Hypothyroidism:** Hypothyroidism occurred in 7% (42/591) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (6%). No patient discontinued treatment and LIBTAYO was withheld in 0.3% of patients due to hypothyroidism. Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 7% of the 42 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 2 patients in whom LIBTAYO was withheld for hypothyroidism, both reinitiated LIBTAYO after symptom improvement; 1 required ongoing hormone replacement therapy; the other did not experience recurrence of hypothyroidism.
- **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 0.7% (4/591) of patients, including Grade 4 (0.5%) and Grade 3 (0.2%). Type 1 diabetes mellitus led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 0.3% of patients. Of the 2 patients in whom LIBTAYO was withheld, both reinitiated LIBTAYO and required insulin treatment.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 65-year-old male with locally advanced CSCC[5]

Anatomically challenging location for surgery and radiotherapy contraindicated

Medical and treatment history

- Patient history indicated that the primary site of the CSCC lesion was on the left cheek
- Tumor staging was T4/N0/M0 at initial diagnosis
- Well-differentiated histology
- Relevant comorbidities (not comprehensive) included allergic rhinitis and sarcoidosis
- Patient underwent a surgical intervention
  – Excision of skin lesion

Patient experienced a series of medical complications

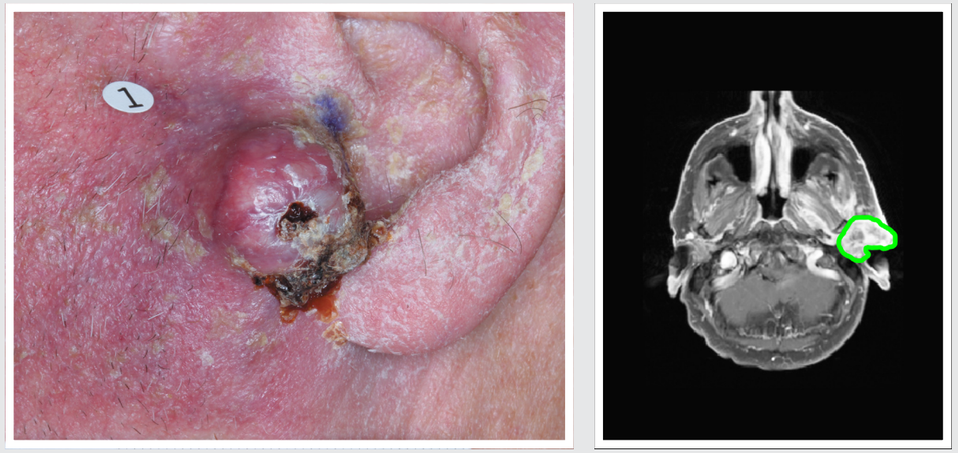
- Grade 2 neuropathy on the left side of the face
- Grade 2 pain on the left side of the face
- Grade 1 left facial paralysis

Patient experienced recurrence/relapse.

Presentation at screening

- Screening -

Anterior auricular lesion[5]



Actual clinical trial patient.

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 0.5% (3/591) of patients receiving LIBTAYO, including Grade 3 (0.3%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 0.3% of patients. Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in all 3 patients. Of the 2 patients in whom LIBTAYO was withheld, none reinitiated LIBTAYO. 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 65-year-old male with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

Patient was a candidate for LIBTAYO due to the following reasons[5]:

- Locally advanced CSCC
- CSCC in an anatomically challenging location; patient not a candidate for surgery, as it was anticipated to result in severe disfigurement or dysfunction
- Individualized benefit-risk assessment was performed by a multidisciplinary team who deemed that radiotherapy was contraindicated
- Tumor staging was T4/NO/MO at clinical trial screening
- Well-differentiated histology at clinical trial screening

Patient received LIBTAYO 3 mg/kg intravenously every 2 weeks in a clinical trial.[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]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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 2.0% (12/591) of patients receiving LIBTAYO, including Grade 3 (1.0%) and Grade 2 (0.8%). Immune-mediated dermatologic adverse reactions led to permanent discontinuation in 0.3% of patients and withholding of LIBTAYO in 1.4% of patients. Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 42% of the 12 patients. Of the 8 patients in whom LIBTAYO was withheld for dermatologic adverse reaction, 5 reinitiated LIBTAYO after symptom improvement; of these 60% (3/5) had recurrence of the dermatologic adverse reaction. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold LIBTAYO for suspected SJS, TEN, or DRESS. Permanently discontinue LIBTAYO for confirmed SJS, TEN, or DRESS. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

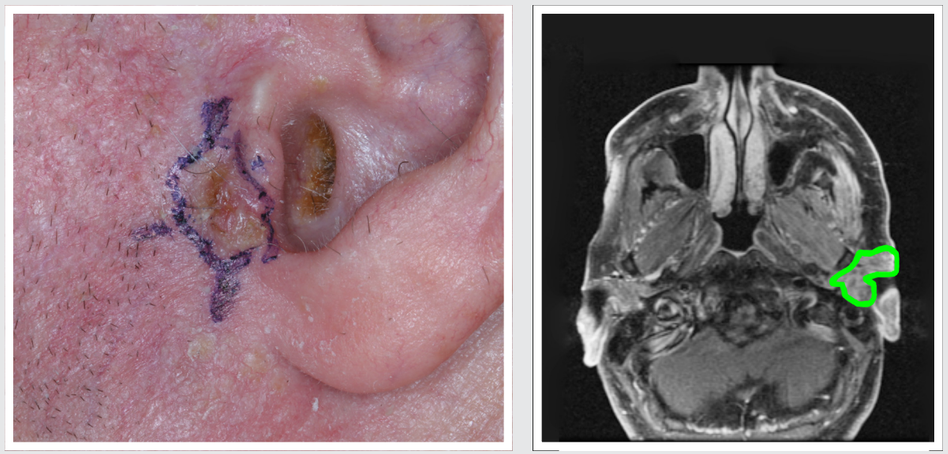
Tumor reduction in a clinical trial patient with locally advanced CSCC who was not a candidate for curative surgery or curative radiation[5]

This is an example from the 15% of patients who had a CR in the combined analysis of patients who received LIBTAYO 3 mg/kg Q2W in Study 1540.[1] Individual patient responses may vary.

By the first assessment, at week 8, a reduction in target lesion of 88.3% from baseline was observed.[5]

- After 8 weeks -

Anterior auricular lesion[5]



Actual clinical trial patient.

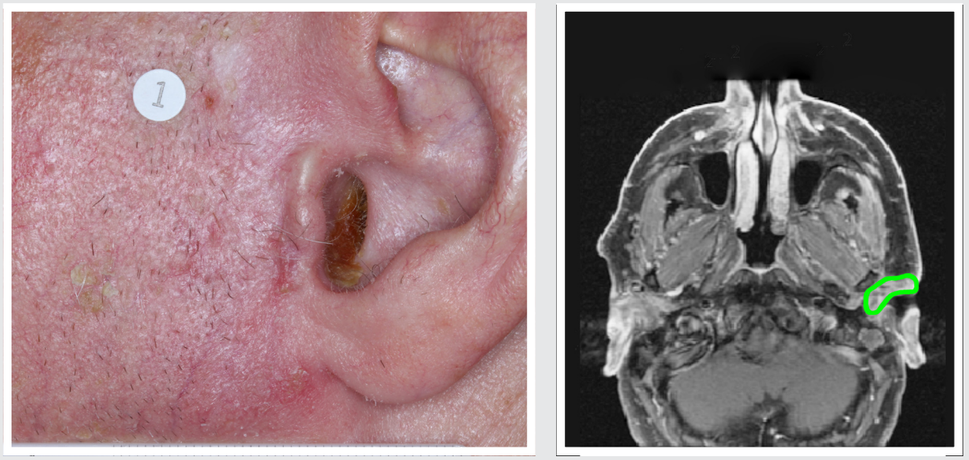
LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor reduction with LIBTAYO[5]

By week 16, target lesion reduction continued with a decrease from baseline of 93.0%.[5]

- After 16 weeks -

Anterior auricular lesion[5]



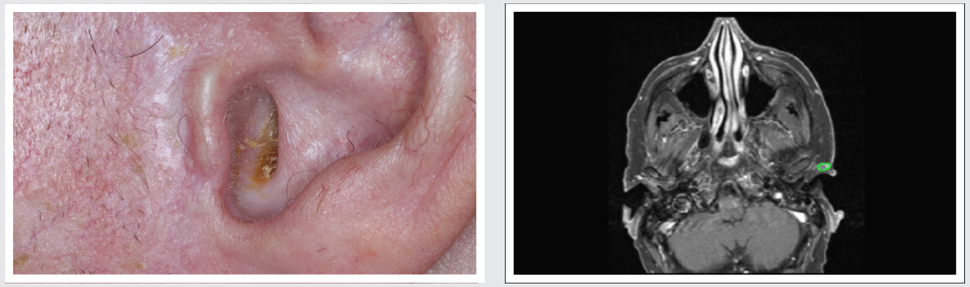
Actual clinical trial patient.

Individual patient responses may vary.

By week 56, target lesion reduction from baseline of 100% was observed. The patient's overall response for this visit was a PR.[5]

- After 56 weeks -

Anterior auricular lesion[5]

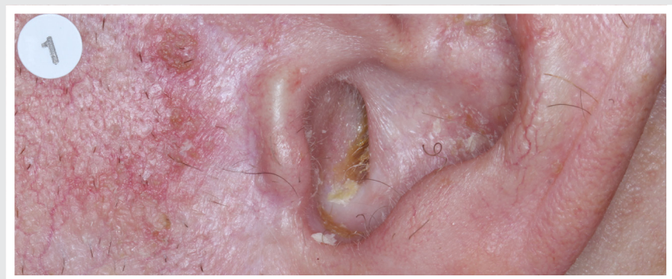


Actual clinical trial patient.

By week 64, target lesion reduction from baseline of 100% was sustained, and the overall response was a CR.[5]

- After 64 weeks* -

Anterior auricular lesion[5]



Actual clinical trial patient.

Clinical outcomes (end of study; as of data cutoff of October 2018)[5]

- Best overall response: CR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percentage change in target lesion(s): –100% per WHO Criteria
- TTR: 8 weeks
- DOR: 15.6 months+

Individual patient responses may vary.

LIBTAYO: A breakthrough for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

*The radiograph at 64 weeks is not available.
Plus sign (+) denotes ongoing at last assessment.[1]

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 591 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 click here for full Prescribing Information.

Case discussion: 85-year-old male with metastatic CSCC[5]

Distant metastasis

Medical and treatment history

- Patient history indicated that the primary site of the CSCC lesion was right temporal
- Tumor staging at initial diagnosis was T1/NX/MX
- Moderately differentiated histology
- Relevant comorbidities (not comprehensive) included type 2 diabetes mellitus (grade 2)

Patient underwent a series of surgical interventions and adjuvant radiotherapy over the course of 10 months

- Head and neck excisional surgery
- Right neck dissection (regions II to V) and parotidectomy
- Adjuvant radiotherapy of the right parotid, cervical (regions II to IV), and supraclavicular regions

Patient experienced a series of medical complications

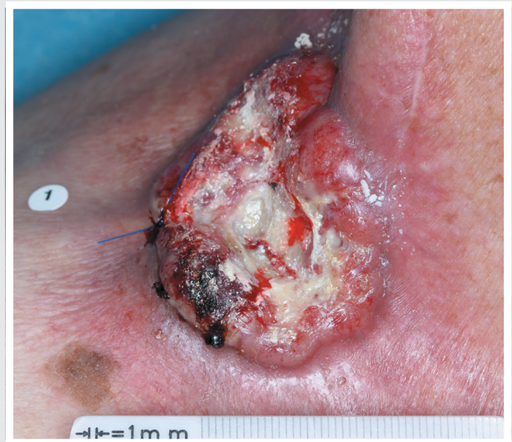
- Grade 2 tumor–associated pain
- Grade 2 right facial paralysis

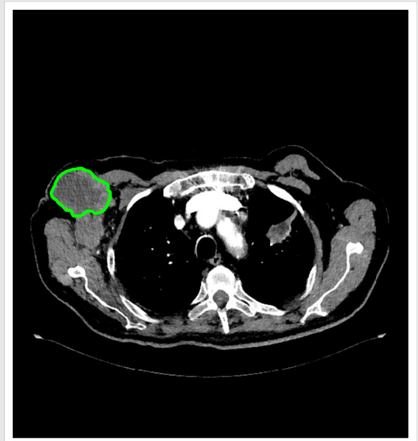
Patient experienced recurrence/relapse.

Presentation at screening

- Screening -

Supraclavicular lesion[5]





Actual clinical trial patient.

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.
- **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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 85-year-old male with metastatic CSCC[5]

Patient was a candidate for LIBTAYO due to the following reasons[5]:

- Metastatic CSCC
  - Cancer spread to the lymph nodes
  - Distant metastasis to the lung
- Tumor stage at clinical trial screening was TX/N3/M1 (2 lesions; largest at baseline was 47.7 mm in diameter)
- Poorly differentiated histology at clinical trial screening

Patient received LIBTAYO 3 mg/kg intravenously every 2 weeks in a clinical trial.[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]

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions (continued):

- **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

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

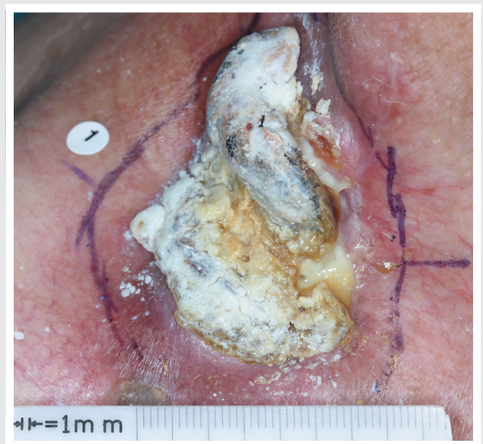
Tumor reduction in a clinical trial patient with metastatic CSCC[5]

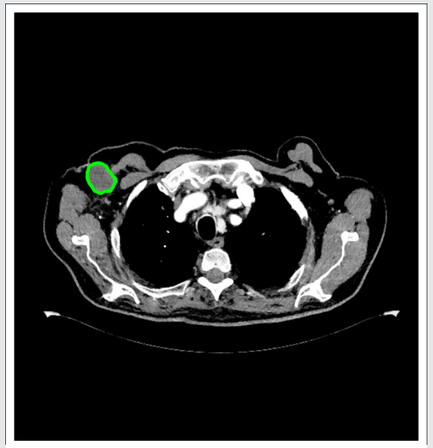
This is an example from the 31% of patients who had a PR in the combined analysis of patients who received LIBTAYO 3 mg/kg Q2W in Study 1540.[1] Individual patient responses may vary.

By the first assessment, at week 8, a reduction in target lesions from baseline of 45.9% was observed.[5]

- After 8 weeks -

Supraclavicular lesion[5]





Actual clinical trial patient.

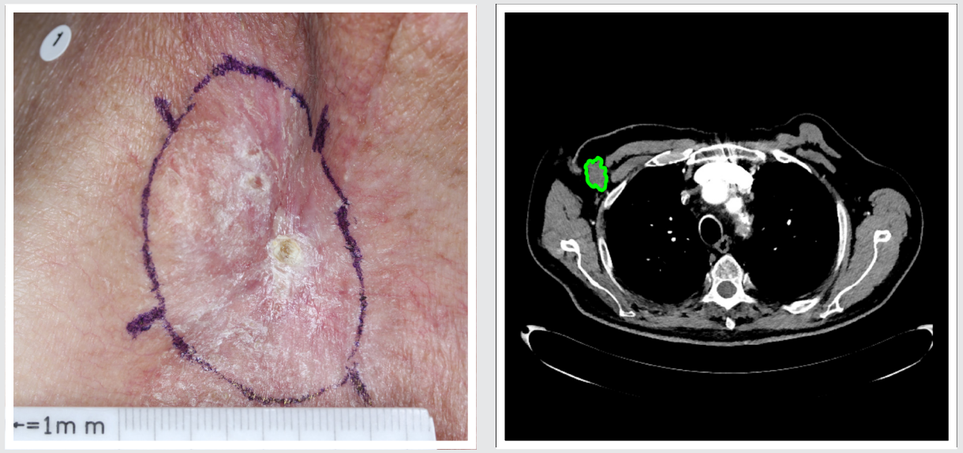
LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor reduction with LIBTAYO[5]

By week 24, a reduction in target lesions from baseline of 65.0% was observed.[5]

- After 24 weeks -

Supraclavicular lesion[5]



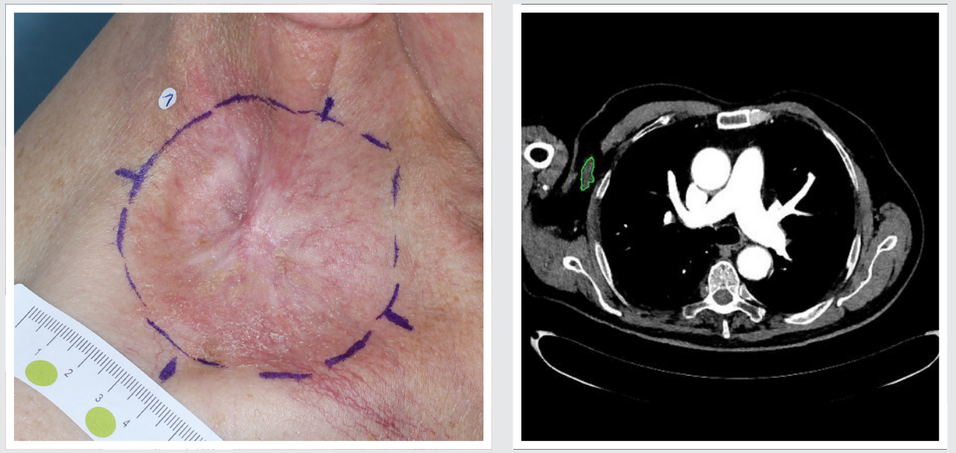
Actual clinical trial patient.

Individual patient responses may vary.

By week 56, target lesion reduction from baseline of 74.9% was observed.[5]

- After 56 weeks -

Supraclavicular lesion[5]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff of September 2018)[5]

- Best response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percentage change in target lesion(s): –74.9% per RECIST 1.1
- TTR: 8 weeks
- DOR: 18.6 months+

Individual patient responses may vary.

LIBTAYO: A breakthrough for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

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

Important Safety Information (continued)

Warnings and Precautions (continued)

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 66-year-old male with metastatic CSCC[5]

Regional and distant metastasis

Medical and treatment history

- Patient history indicated that the primary site of the CSCC lesion was the right side of the face
- Tumor staging at initial diagnosis was TX/N2/M0
- Moderately differentiated histology
- Relevant comorbidities (not comprehensive) included renal cell carcinoma and malignant oral neoplasms

Patient underwent a series of surgical interventions and chemotherapy over the course of 2 years

- 2 surgical excisions of CSCC lesions
- Lymph node biopsy and subsequent right neck dissection
- Systemic treatment with cisplatin for nodal disease

Patient reported mild neck pain (grade 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.

Embryo-fetal toxicity

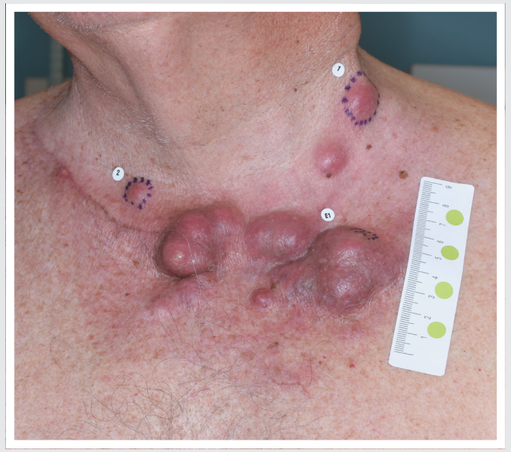
LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment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

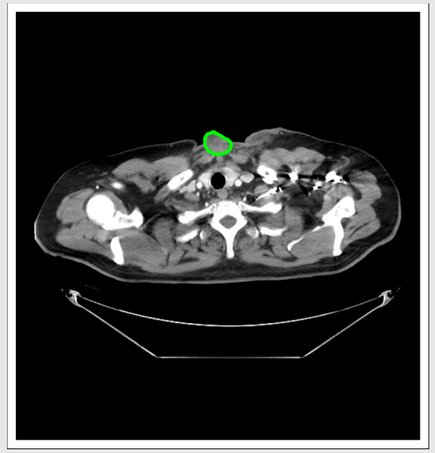
Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Presentation at screening

- Screening -

Numerous periclavicular lesions[5]





Actual clinical trial patient.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Case discussion: 66-year-old male with metastatic CSCC[5]

Patient was a candidate for LIBTAYO due to the following reasons[5]:

- Distant metastatic CSCC
  - Subcutaneous metastases
  - Cancer spread to the lymph nodes
- Presented with numerous lesions on the periclavicular region
- Tumor stage at screening was T2/N2/M1
- Moderately differentiated histology at clinical trial screening

Patient received LIBTAYO 3 mg/kg intravenously every 2 weeks in a clinical trial.[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]

Important Safety Information (continued)

Adverse reactions

- Serious adverse reactions occurred in 35% of patients. Serious adverse reactions that occurred in ≥2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia
- LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients; adverse reactions 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
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, diarrhea, musculoskeletal pain, and nausea

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

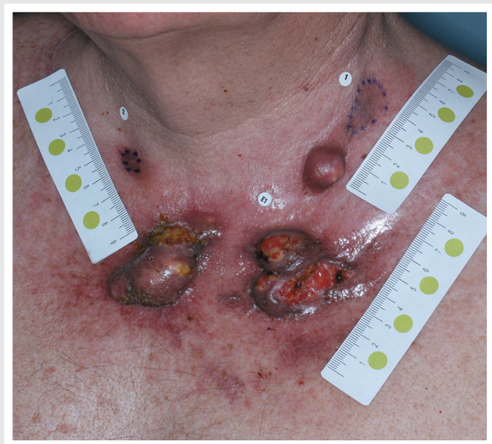
Tumor reduction in a clinical trial patient with metastatic CSCC[5]

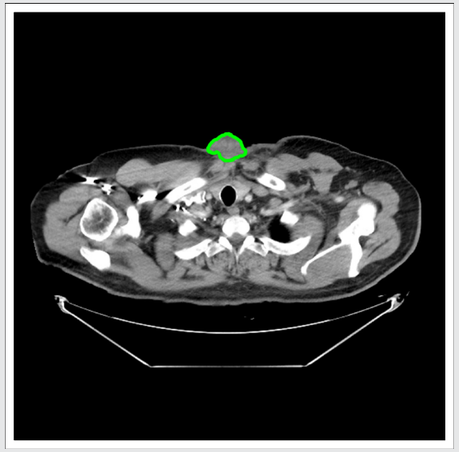
This is an example from the 15% of patients who had a CR in the combined analysis of patients who received LIBTAYO 3 mg/kg Q2W in Study 1540.[1] Individual patient responses may vary.

By the first assessment, at week 8, the patient had not yet responded.[5]

- After 8 weeks -

Numerous periclavicular lesions[5]





Actual clinical trial patient.

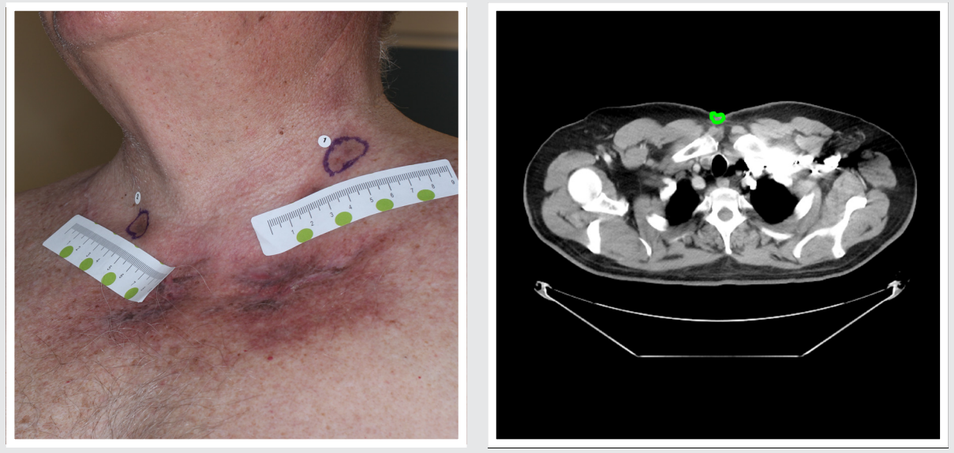
LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Tumor reduction with LIBTAYO[5]

By week 24, a reduction in target lesions from baseline of 71.1% was observed.[5]

- After 24 weeks -

Numerous periclavicular lesions[5]



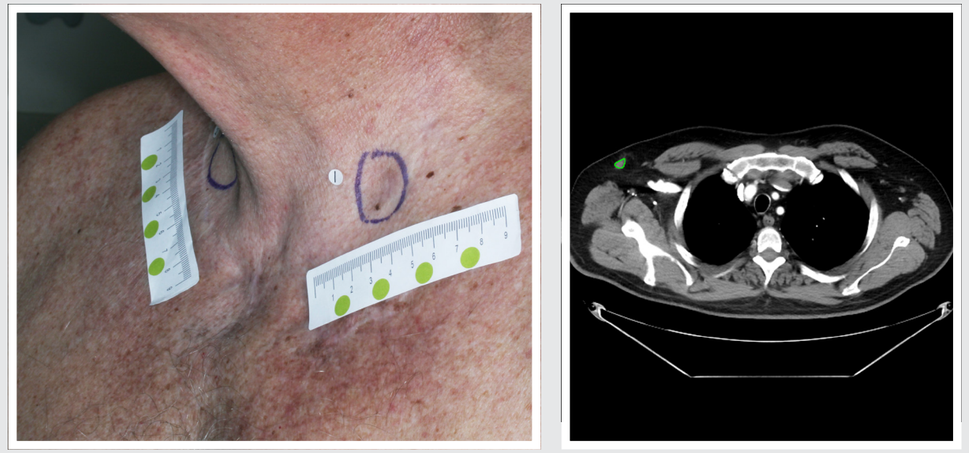
Actual clinical trial patient.

Individual patient responses may vary.

By week 64, a reduction in target lesions from baseline of 100% was observed.[5]

- After 64 weeks -

Numerous periclavicular lesions[5]



Actual clinical trial patient.

Clinical outcomes (as of data cutoff of September 2018)[5]

- Best response: CR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percentage change in target lesions: –100% per RECIST 1.1
- TTR: 24 weeks (5.5 months)
- DOR: 16.6 months+

Individual patient responses may vary.

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 click here for full Prescribing Information.

LIBTAYO: A breakthrough for patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]

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

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** 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. **3.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Updated July 16, 2020. Accessed October 15, 2020. **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 October 15, 2020. **5.** Data on file. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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(cemiplimab-rwlc)
Injection 350 mg

To learn more about LIBTAYO, visit **LIBTAYOhcp.com**

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