LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

NOW APPROVED in Metastatic BCC

LIBTAYO is approved for patients with metastatic basal cell carcinoma (mBCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate.

- This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for the mBCC indication may be contingent upon verification and description of clinical benefit[1]

Important Safety Information

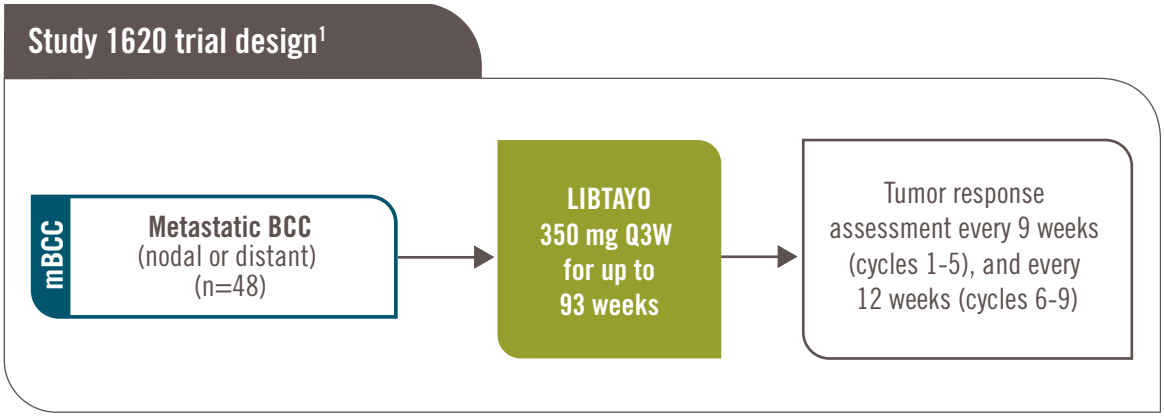
Warnings and Precautions

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.

LIBTAYO was studied in a prospective clinical trial in patients with mBCC previously treated with an HHI



Primary endpoint[1]

- Confirmed ORR as assessed by ICR

Secondary endpoints included[2]

- 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 48 patients had metastatic BCC that had progressed on HHI therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1,2]

Study 1620 excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/PD-L1 therapy or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or Eastern Cooperative Oncology Group Performance Status ≥2.[1]

BCC=basal cell carcinoma; ICR=independent central review; laBCC=locally advanced BCC; mBCC=metastatic BCC; ORR=objective response rate; PD-1=programmed death receptor-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)

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.

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Baseline characteristics of patients with mBCC previously treated with an HHI enrolled in Study 1620[1]

	Metastatic BCC (n=28)
Metastatic BCC	
Distant metastases only, %	32
Nodal disease only, %	14
Both distant and nodal disease, %	54
Median age, years (range)	65.5 (38-90)
Male, %	82
White, %	79
ECOG performance status, %	
0	57
1	43
PRIOR TREATMENTS Prior cancer-related surgery or radiotherapy	
Patients with at least 1 prior surgery, %	82
Patients with at least 1 prior radiotherapy, %	61

*Investigators were allowed to select more than one reason for discontinuation of prior HHI therapy for an individual patient.[2]

BCC=basal cell carcinoma; ECOG=Eastern Cooperative Oncology Group.

Reason for HHI discontinuation*

All patients were previously treated with HHIs (n=28)[1]

93%
Disease progression/ lack of response[2]

7%
Intolerance to HHI therapy[2]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

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.

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Efficacy results for LIBTAYO in patients with metastatic BCC previously treated with an HHI[1]

Confirmed objective response rate (ORR)[1]	Metastatic BCC* (n=28)
ORR, n (%)	6 (21%) (95% CI, 8-41)
Complete response, n (%)	0
Partial response, n (%)	6 (21%)

- Median duration of follow-up was 9.5 months[1]

Observed duration of response[1]	Metastatic BCC*
≥6 months	100% of responders (6 out of 6)

- Median DOR was not reached (range: 9.0-23.0+ months)[1]
- Median TTR was 3.2 months (range: 2.1-10.5 months)[1]

ORR is determined by the proportion of patients with best objective 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.[2]

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 (<1 cm). Only includes patients with complete healing of prior cutaneous involvement; patients with locally advanced BCC in the study required biopsy to confirm CR.[2]

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 dimensions of target lesions, per WHO Criteria. Nontarget lesions could not have PD, and there could be no new lesions. Responses had to be maintained for at least 4 weeks.[2]

*Efficacy analysis included 28 patients.[1]
Plus sign (+) denotes ongoing at last assessment.[1]

BCC=basal cell carcinoma; CI=confidence interval; CR=complete response; DOR=duration of response; PD=progressive disease; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; TTR=time to response; WHO=World Health Organization.

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.

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Adverse reactions in patients receiving LIBTAYO in Study 1620[1]*

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, 48 patients had mBCC.[1]**

- 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[1]
- Fatal ARs occurred in 1.5% of patients who received LIBTAYO, including acute kidney injury and cachexia[1]
- Permanent discontinuation of LIBTAYO due to an AR occurred in 13% of patients[1]
- ARs resulting in permanent discontinuation of LIBTAYO in >1.5% (at least 2 patients) were colitis and general physical health deterioration[1]

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03.[1]
†Fatigue is a composite term that includes fatigue, asthenia, and malaise.[1]
‡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.[1]
§Rash is a composite term that includes rash maculopapular, rash, dermatitis, dermatitis acneiform, erythema, rash pruritic, dermatitis bullous, dyshidrotic eczema, pemphigoid, rash erythematous, and urticaria.[1]
‖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.[1]
¶Dyspnea is a composite term that includes dyspnea and dyspnea exertional.[1]
#Hypertension is a composite term that includes hypertension and hypertensive crisis.[1]
AR=adverse reaction; BCC=basal cell carcinoma.

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Grade 3 or 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, 48 patients had mBCC.[1]**

- Dosage delays of LIBTAYO 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[1]
- The most common ARs reported in at least 15% of patients were fatigue, musculoskeletal pain, diarrhea, rash, pruritus, and upper respiratory tract infection[1]
- The most common Grade 3 or 4 ARs (>2%) were hypertension, colitis, fatigue, urinary tract infection, pneumonia, increased blood pressure, hypokalemia, and visual impairment[1]
- The most common (>3%) laboratory abnormality worsening from baseline to Grade 3 or 4 was hyponatremia[1]

Toxicity graded per NCI CTCAE v. 4.03.[1]
†Percentages are based on the number of patients with at least 1 postbaseline value available for that parameter.[1]
AR=adverse reaction; BCC=basal cell carcinoma.

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.

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.

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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.

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

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

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

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.
- **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.

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Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (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 0.7% (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.

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.

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.

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

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% 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.

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Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (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.

Adverse reactions

- **In Study 1423 and Study 1540:** Serious adverse reactions occurred in 35% of patients. Serious adverse reactions that occurred in ≥2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia. 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. The most common Grade 3-4 adverse reactions (≥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.
- **In Study 1620:** Serious adverse events occurred in 32% of patients. Serious adverse reactions that occurred in >1.5% (at least 2 patients) were urinary tract infection, colitis, acute kidney injury, adrenal insufficiency, anemia, infected neoplasm, and somnolence. Fatal adverse reactions occurred in 1.5% of patients who received LIBTAYO, including acute kidney injury and cachexia. Permanent discontinuation of LIBTAYO due to an adverse reaction occurred in 13% of patients. Adverse reactions resulting in permanent discontinuation of LIBTAYO in >1.5% (at least 2 patients) were colitis and general physical health deterioration. Dosage delays of LIBTAYO due to an adverse reaction occurred in 34% of patients. Adverse reactions 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 adverse reactions 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 adverse reactions (>2%) were hypertension, colitis, fatigue, urinary tract infection, pneumonia, increased blood pressure, hypokalemia and visual impairment. The most common (>3%) laboratory abnormality worsening from baseline to Grade 3 or 4 was hyponatremia.

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 additional Important Safety Information throughout and accompanying full Prescribing Information.

Indication and Usage

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

- The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for the mBCC indication may be contingent upon verification and description of clinical benefit.

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References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Data on file. Regeneron Pharmaceuticals, Inc.

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.[1]

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

HSCT=hematopoietic stem cell transplantation.

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