Living With Advanced Basal Cell Carcinoma:

A Patient's Treatment Journey

Patient Ambassador Webinar

10/27/2023

US.LIB.23.11.0005 11/23

Disclosures

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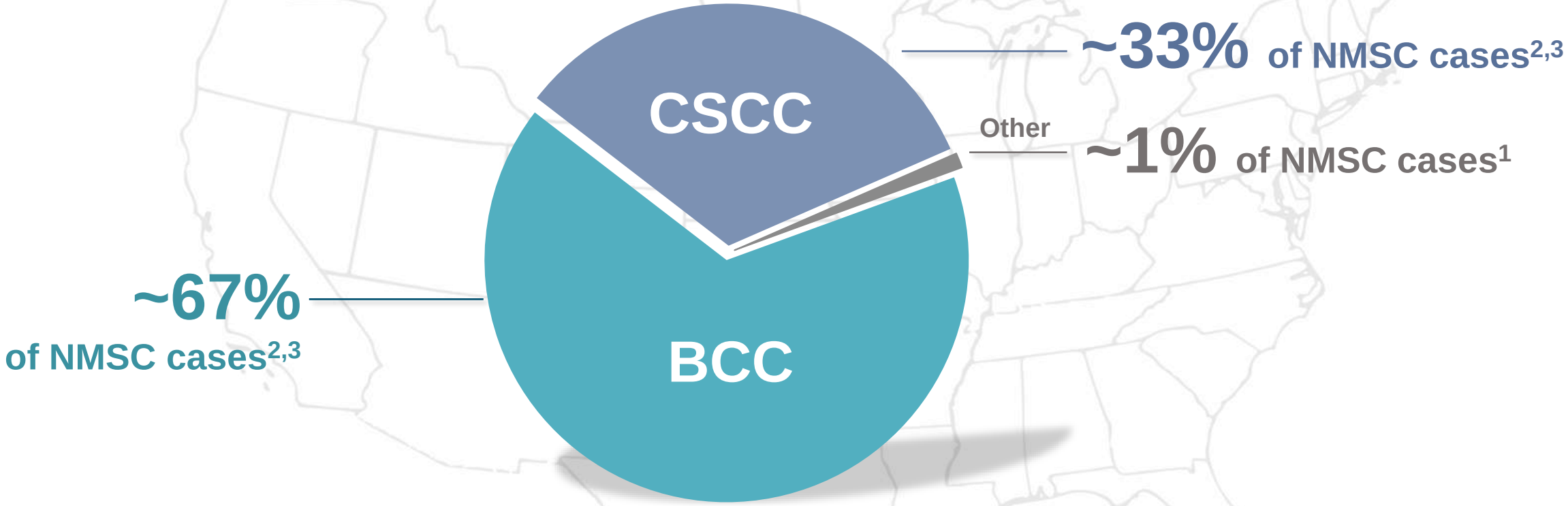
Objectives

1. Identifying patients at high risk for developing advanced BCC
2. Review the importance of a multidisciplinary approach in the management of patients with advanced BCC
3. Review considerations for systemic therapy in patients with advanced BCC
4. Review the clinical and safety data of a systemic therapy option in advanced BCC
5. Hear firsthand experiences from a patient living with advanced BCC

BCC, basal cell carcinoma.

BCC Is the Most Common Form of Nonmelanoma Skin Cancer[1,2]



~33% of NMSC cases[2,3]

~1% of NMSC cases[1]

~67% of NMSC cases[2,3]

Every year in the United States,

>2 million patients are diagnosed with a BCC[4]

CSCC, cutaneous squamous cell carcinoma; NMSC, nonmelanoma skin cancer.

References: 1. Fahradyan A, et al. *Healthcare (Basel)*. 2017;5(4):82. **2.** Our new approach to a challenging skin cancer statistic. The Skin Cancer Foundation. April 1, 2021. Accessed March 22, 2023. https://www.skincancer.org/blog/our-new-approach-to-a-challenging-skin-cancer-statistic. **3.** Lukowiak TM, et al. *JAMA Dermatol*. 2020;156(11):1192-1198. **4.** Migden MR, et al. *Cancer Treat Rev*. 2018;64:1-10.

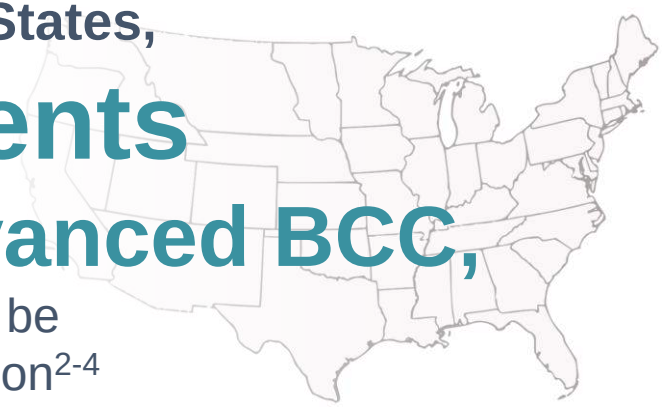
While Early-stage BCC May Be Cured by Surgery or Radiation, Progression to Advanced BCC May Lead to Poor Prognosis[1,2]

Every year in the United States,

>20,000 patients

progress to advanced BCC,

some of whom may no longer be amenable to surgery or radiation[2-4]



Locally advanced BCC

Large, aggressive, or recurrent tumors, or those that penetrate deeper into the underlying skin and surrounding tissue[2-3]

In advanced BCC, patients reported impacts across numerous domains, including[5]:

- Daily activities
- Emotional well-being
- Social/leisure activities
- Cosmetic/function

References: 1. Califano JA, et al. In: Amin MB, et al, eds. *AJCC Cancer Staging Manual*. 8th ed. New York, NY: Springer; 2017:171-181. **2.** Migden MR, et al. *Cancer Treat Rev*. 2018;64:1-10. **3.** Cameron MC, et al. *J Am Acad Dermatol*. 2019;80(2):303-317. **4.** Asgari MM, et al. *JAMA Dermatol*. 2015;151(9):976-981. **5.** Steenrod AW, et al. *Dermatol Ther (Heidelb)*. 2015;5(3):183-199.

Several Factors Are Associated with an Increased Risk of Recurrence[1]

LOCATION

- Head, neck, hands, feet, pretibial, and anogenital area (any size)

SIZE

- ≥20 mm (trunk and extremities)

PATHOLOGY

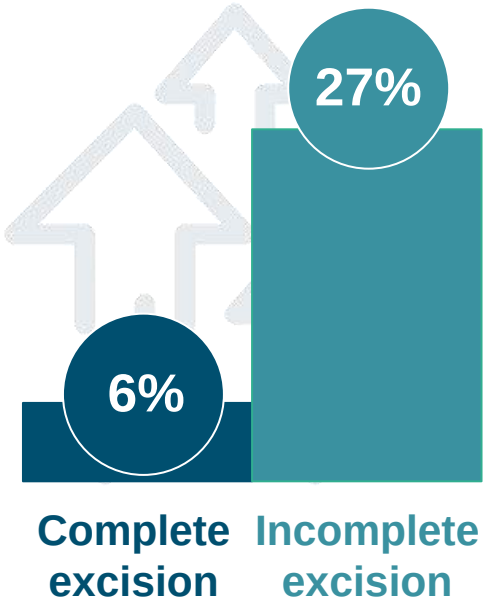
- Aggressive growth pattern*
- Poorly defined borders
- Perineural involvement

HISTORY

- Recurrent disease
- Site of prior radiotherapy
- Immunosuppression

Patients with even a single risk factor are deemed high-risk

Incomplete surgical resection increases the likelihood of disease recurrence[2]

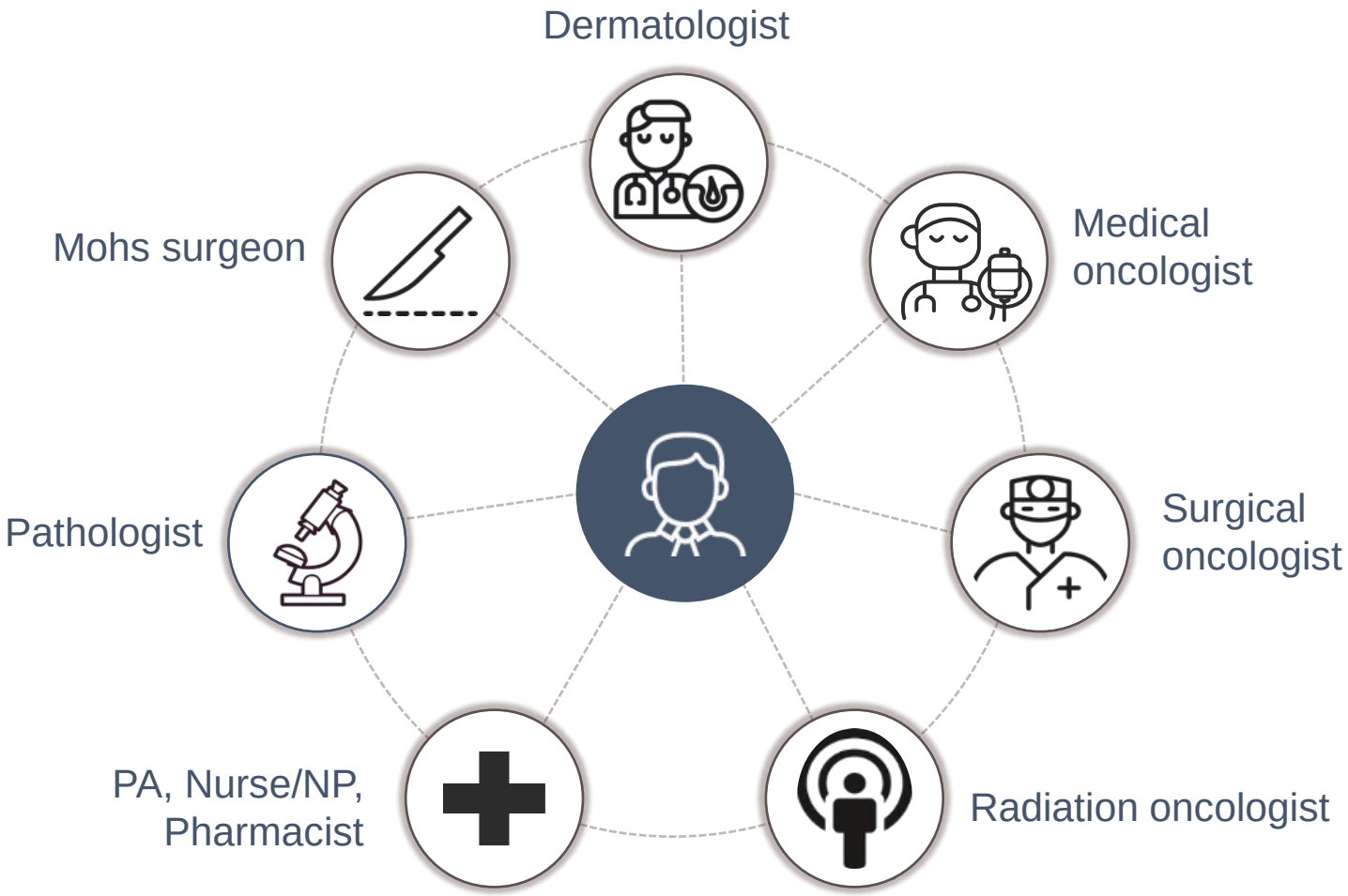


*Having basosquamous, infiltrative, sclerosing/morpheaform, micronodular, and BCC with carcinosarcomatous differentiation features in any portion of the tumor.[1]

NCCN, National Comprehensive Cancer Network® (NCCN®).

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Basal Cell Skin Cancer V.2.2024. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed September 14, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** Codazzi D, et al. *J Plast Surg Hand Surg*. 2014;48(1):38-43.

Guidelines Unanimously Recommend a Multidisciplinary Approach in the Management of Advanced BCC[1-3]



- ✓ American Academy of Dermatology (AAD)[1]
- ✓ National Comprehensive Cancer Network® (NCCN®)[2,*]
- ✓ European Dermatology Forum (EDF)[3]
- ✓ European Association of Dermato Oncology (EADO)[3]
- ✓ European Organisation for Research and Treatment of Cancer (EORTC)[3]

*NCCN Guidelines® do not specify a specific list of disciplines that must be included in a multidisciplinary tumor board.

NP, nurse practitioner; PA, physician assistant.

References: 1. Bichakjian C, et al. *J Am Acad Dermatol*. 2018;78(3):540-559. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Basal Cell Skin Cancer V.2.2024. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed September 14, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Peris K, et al. *Eur J Cancer*. 2019;118:10-34.

FPO:
Speaker
Image

Can you tell us more about your diagnosis experience?

Were you cared for by a multidisciplinary team?

QUESTION & ANSWER

SESSION

Systemic Therapies Can Play a Critical Role in the Management of Advanced BCC Once a Patient Is No Longer a Candidate for Surgery or Radiation

Considerations for systemic therapy decision

Tumor characteristics[1-3]

- Large tumors
- Significant local invasion
- Potential for deformity/morbidity
- Aggressive growth
- Multiple BCC tumors

Patient characteristics[2]

- Age
- Comorbidities
- Performance status
- Patient treatment preference

Treatment history[1,2]

- Multiple recurrences
- Prior radiotherapy
- Prior surgery

References: 1. Migden MR, et al. *Cancer Treat Rev*. 2018;64:1-10. **2.** Lear JT, et al. *Br J Cancer*. 2014;111(8):1476-1481. **3.** Peris K, et al. *Eur J Cancer*. 2019;118:10-34.

A Multidisciplinary Treatment Plan Is Recommended for Patients with Advanced BCC Who Discontinue or Are Inappropriate for HHI Therapy

Surgery/radiation → **HHI therapy** → **Subsequent therapy**

Patient with aBCC

Not a candidate for surgery or radiation

Prescribed
HHI therapy[1,2]

Dose adjustments/ treatment holidays

Treatment discontinuation[3-6]

- ❑ Intolerance
- ❑ Disease progression
- ❑ Patient withdrawal

While HHIs are an important part of the treatment algorithm, ~**90%** of patients ultimately discontinue HHI therapy[3-5]

Inappropriate
for HHI therapy

Clinician judgment can help determine whether a patient is inappropriate for HHI therapy[8]

ONLY

~1 in 10

patients who discontinue HHI therapy receive another treatment[7]

Multidisciplinary teams help evaluate treatment options for patients who discontinue or are inappropriate for HHI therapy

HHI, hedgehog pathway inhibitor.

References: 1. Erivedge [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2020. **2.** Odomzo [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022. **3.** Lear JT, et al. *J Eur Acad Dermatol Venereol*. 2018;32(2):372-381. **4.** Sekulic A, et al. *BMC Cancer*. 2017;17(1):332. **5.** Lewis K, et al. *Dermatol Ther (Heidelb).* 2021;11(6):2225-2234. **6.** Lacouture ME, et al. *Oncologist.* 2016;21(10):1218-1229. **7.** Cowey CL, et al. *Dermatol Ther (Heidelb).* 2022;12(5):1211-1224. . **8.** Treating Basal and Squamous Cell Skin Cancer. American Cancer Society. Accessed September 15, 2023. https://www.cancer.org/content/dam/CRC/PDF/Public/8821.00.pdf.

FPO:
Speaker
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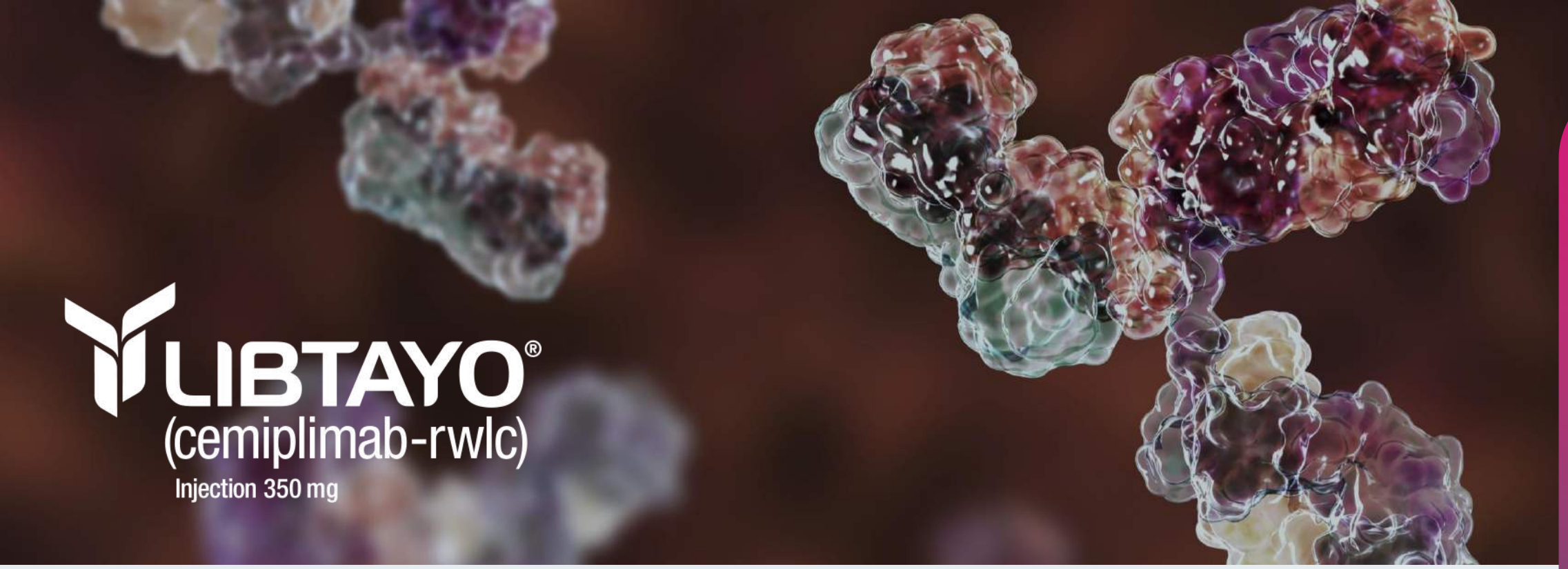
Can you tell us more about your treatment experience with HHIs?

QUESTION & ANSWER

SESSION



LIBTAYO is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with:

- Locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate
- Metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

LIBTAYO Is FDA-approved in Advanced BCC and Advanced CSCC[1]

Advanced BCC

LIBTAYO is the FIRST & ONLY treatment indicated for patients with laBCC or mBCC[1]

who have been previously treated with an HHI — OR — for whom an HHI is not appropriate

Advanced CSCC

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

>8 Years of clinical treatment experience[1,2,*]

#1 LIBTAYO is the most prescribed immunotherapy by oncologists for patients across both advanced BCC and advanced CSCC[3,†]

>20,000 patients treated across all FDA-approved indications[1,3,†,‡]

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

†Estimate based on IQVIA medical claims data from October 2018 through May 2023 and calibrated with actual vials sold.[3] ‡Since its first approval in 2018.

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

FDA, Food and Drug Administration.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Study of REGN2810 (anti-PD-1) in patients with advanced malignancies. ClinicalTrials.gov. Updated January 27, 2020. Accessed March 22, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT02383212. **3.** Data on file. Regeneron Pharmaceuticals, Inc.

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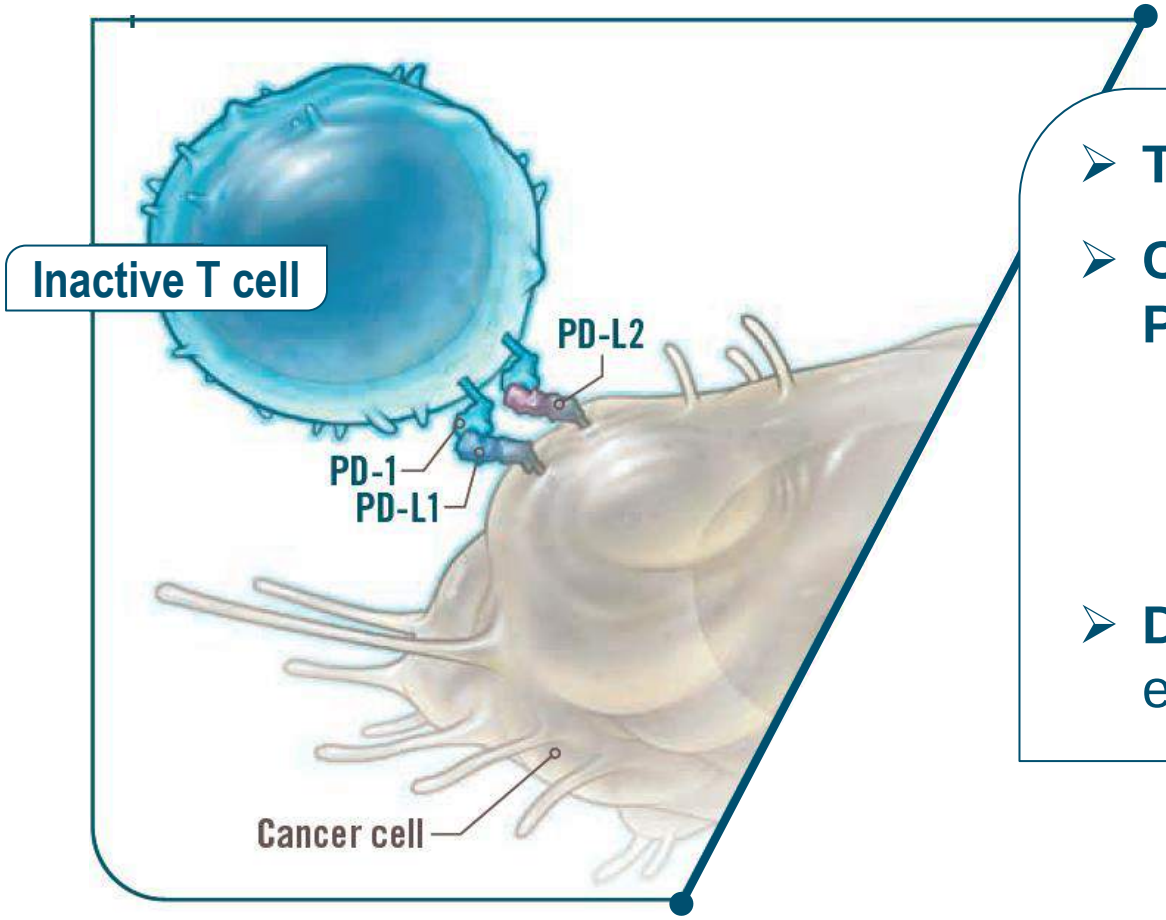
Cancer Cells Evade the Immune System via the PD-1 Pathway[1,2]



- **T cells attack and kill abnormal cells**
- **Cancer cells can avoid this attack via the PD-1 pathway**
  - The PD-1 pathway leads to inactivation of T cells when the PD-1 receptor (found on T cells) interacts with its ligands, PD-L1 and PD-L2 (expressed on tumor cells)[2]
- **Disrupting these immune checkpoints** may help enhance immune responses and tumor destruction

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

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

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Pardoll DM. *Nat Rev Cancer.* 2012;12(4):252-264.

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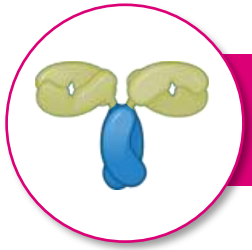
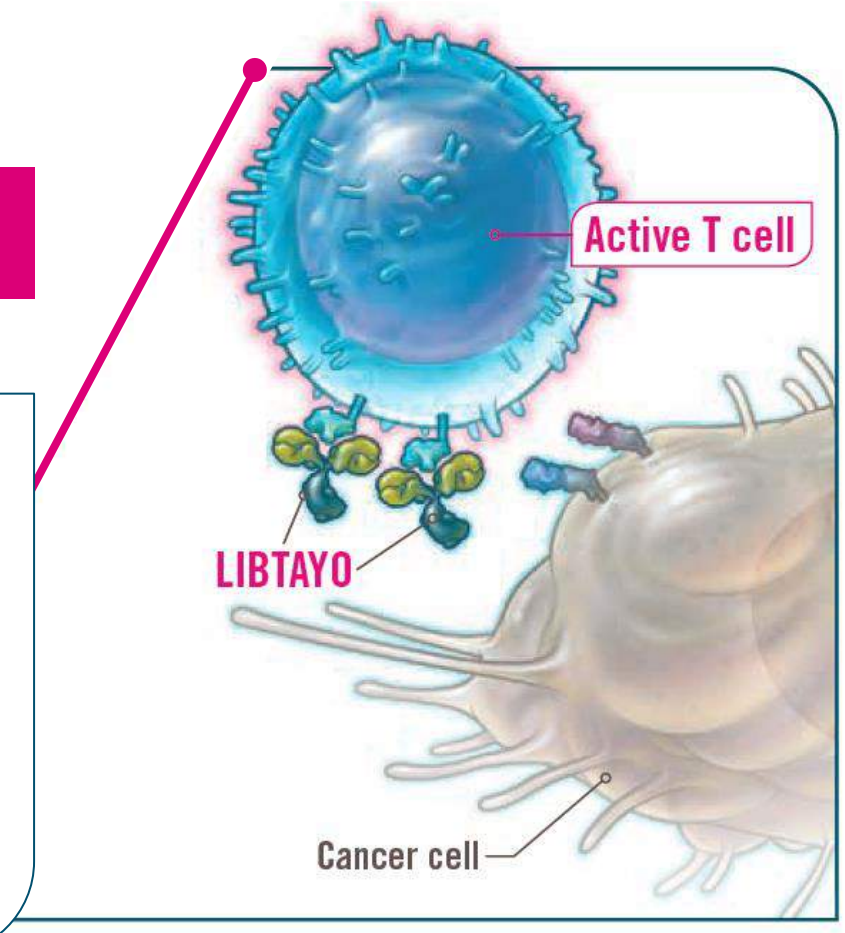
LIBTAYO Helps to Restore the Antitumor T-cell Response[1]



LIBTAYO is a fully-human monoclonal antibody
generated using Regeneron's proprietary VelocImmune® technology[2]

- **LIBTAYO is a recombinant human IgG4 monoclonal antibody that acts by blocking the PD-1 pathway**
- LIBTAYO binds to PD-1 receptors on T cells, blocking their interaction with PD-L1 and PD-L2 on tumor cells, thereby helping to restore antitumor T-cell response[2]



Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

IgG4, immunoglobulin G4.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Burova E, et al. *Mol Cancer Ther.* 2017;16(5):861-870.

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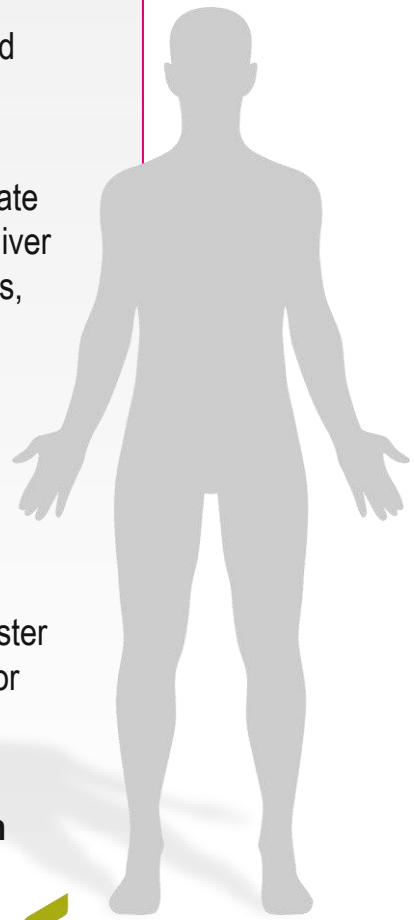
Important Safety Information

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.
- **No dose reduction for LIBTAYO is recommended.** In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids.
- **Withhold or permanently discontinue LIBTAYO depending on severity.** In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.
- **The incidence and severity of immune-mediated adverse reactions were similar when LIBTAYO was administered as a single agent or in combination with chemotherapy.**



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Please see additional Important Safety Information throughout and full Prescribing Information available at this presentation.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

LIBTAYO Was Validated in the Largest Prospective Clinical Study of a PD-1 Inhibitor[1,2]

Study 1620: A phase 2, global, pivotal, open-label, nonrandomized, multicohort study

Patients with laBCC (n=84) or mBCC (n=54) who

- Had **progressed** on HHI therapy

– or –

- Had **not had an objective response** after 9 months of HHI therapy

– or –

- Were **intolerant** of prior HHI therapy

LIBTAYO 350 mg Q3W

Treatment continued up to 93 weeks, until:

- ❑ Progression of disease, or
- ❑ Unacceptable toxicity, or
- ❑ Completion of planned treatment

OUTCOME MEASURES*

PRIMARY ENDPOINT

- ❑ Confirmed objective response rate (ORR)†

SECONDARY ENDPOINTS INCLUDED

- ❑ Duration of response (DOR)
- ❑ Complete response (CR) rate
- ❑ Safety and tolerability

KEY EXCLUSION CRITERIA

Autoimmune disease requiring systemic therapy with immunosuppressant agents within 5 years | Prior treatment with PD-1/PD-L1–blocking inhibitor or immunosuppressant | History of solid organ transplant | Infection with HIV, hepatitis B virus, or hepatitis C virus | ECOG performance status ≥2

No PD-L1 or TMB testing is required before starting LIBTAYO in advanced BCC

*Tumor response assessed every 9 weeks (cycles 1-5) and every 12 weeks (cycles 6-9) using RECIST 1.1 for scans, modified WHO Criteria for photos of externally visible lesions, and composite (RECIST 1.1 + WHO Criteria) when both scans and photos were feasible. †Assessed by independent central review.

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

ECOG, Eastern Cooperative Oncology Group; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumours; TMB, tumor mutational burden; WHO, World Health Organization.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Stratigos AJ, et al. *Lancet Oncol*. 2021;22(6):848-857.

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LIBTAYO Demonstrated Clinically Meaningful and Durable Responses in Locally Advanced BCC[1,2,*]

Locally advanced BCC (n=84)

Median follow-up: 15.9 months

OBJECTIVE RESPONSE RATE

32%

(95% CI, 22-43)

PARTIAL RESPONSE (n=21)

25% of patients had a **reduction in tumor size**

COMPLETE RESPONSE (n=6)

7% of patients had a **disappearance of tumors**

The percentage of patients with laBCC responding to LIBTAYO (ORR) increased from 29% at primary analysis to 32% at the 1-year data readout[2,3]

Exploratory Subgroup Analysis of ORR by Reason for Prior HHI Discontinuation[4].

Limitation: This analysis did not have enough power for hypothesis tests. No firm conclusions can be made.

Progression/lack of response (75% of the patients with laBCC) → **30% ORR** (19/63)

Intolerance (25% of the patients with laBCC) → **38% ORR** (8/21)

TIME TO RESPONSE

MEDIAN 4.3 months

(range: 2.1-21.4)

OBSERVED DURATION OF RESPONSE

Response durations for responders ranged from **2.1 to 36.8+ months (median not reached)**

Plus sign (+) denotes ongoing at last assessment.

*Data cutoff was May 2021.[2]

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Stratigos AJ, et al. EADO. 2022 (abstr Id. 29). **3.** Stratigos AJ, et al. *Lancet Oncol*. 2021;22(6):848-857. **4.** Data on file. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO Demonstrated Clinically Meaningful and Durable Responses in Metastatic BCC[1,2,*]

Metastatic BCC (n=54)

Median follow-up: 8.4 months

OBJECTIVE RESPONSE RATE

24%

(95% CI, 13-38)

PARTIAL RESPONSE (n=12)

22% of patients had a **reduction in tumor size**

COMPLETE RESPONSE (n=1)

2% of patients had a **disappearance of tumors**

TIME TO RESPONSE

MEDIAN 4.0 months

(range: 2.0-10.5)

OBSERVED DURATION OF RESPONSE

Response durations for responders ranged from **4.8 to 25.8+ months (median DOR: 16.7 months)**

Plus sign (+) denotes ongoing at last assessment.

*Data cutoff was May 2021.[2]

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Lewis KD, et al. Poster. AACR. 2022 (abstr CT165).

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO Demonstrated a Favorable Safety Profile in Study 1620

Adverse Reactions in ≥10% of Patients with Advanced BCC Receiving LIBTAYO (N=138)

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

Toxicity was graded per NCI CTCAE v.4.03.

*Includes fatigue, asthenia, and malaise. †Includes peripheral edema, peripheral swelling, and face swelling. ‡Includes arthralgia, back pain, pain in extremity, myalgia, neck pain, non-cardiac chest pain, arthritis, musculoskeletal chest pain, musculoskeletal stiffness, musculoskeletal discomfort, and spinal pain. §Includes diarrhea, colitis, autoimmune colitis, and enterocolitis. ‖Includes abdominal pain, abdominal pain upper, abdominal pain lower, and gastrointestinal pain. ¶Includes rash maculo-papular, eczema, rash, dermatitis, erythema, dermatitis acneiform, rash pruritic, rash pustular, dermatitis bullous, dyshidrotic eczema, pemphigoid, rash erythematous, urticaria, nodular rash, and skin exfoliation. #Includes upper respiratory tract infection, influenza like illness, nasopharyngitis, rhinitis, sinusitis, viral rhinitis, pharyngitis, laryngitis, respiratory tract infection, influenza, viral upper respiratory tract infection, and influenza A virus test positive. **Includes urinary tract infection, cystitis, and urosepsis. ††Includes tumor hemorrhage, hematuria, epistaxis, eye hemorrhage, hemoptysis, hemorrhage intracranial, hemorrhagic diathesis, postmenopausal hemorrhage, rectal hemorrhage, skin hemorrhage, skin neoplasm bleeding, ulcer hemorrhage, vaginal hemorrhage, wound hemorrhage, and subcutaneous hematoma. ‡‡Includes hypertension, blood pressure increased, and hypertensive crisis. §§Includes dyspnea and dyspnea exertional. ‖‖Includes blood creatinine increased, acute kidney injury, renal failure, renal impairment, glomerular filtration rate decreased, and nephropathy toxic. ¶¶Includes dizziness, and vertigo. ##Includes paresthesia, dysesthesia, hypoesthesia, peripheral motor neuropathy, burning sensation, neuralgia, and peripheral sensory neuropathy. ***Includes hypothyroidism, blood thyroid stimulating hormone increased, and immune-mediated hypothyroidism. †††Includes alanine aminotransferase increased, aspartate aminotransferase increased, bilirubin conjugated increased, blood alkaline phosphatase increased, blood bilirubin increased, and gamma-glutamyltransferase increased.

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.

See additional Important Safety Information throughout this presentation and in Section 5 of the accompanying full Prescribing Information for more information on Warnings and Precautions.

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

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Grade 3-4 Laboratory Abnormalities in Study 1620

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

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

Toxicity graded per NCI CTCAE v.4.03.

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

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

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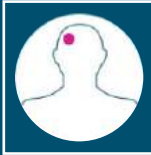
FPO:
Speaker
Image

How were you introduced to LIBTAYO?

QUESTION & ANSWER SESSION

CASE STUDY 1

66-Year-Old Patient with Locally Advanced BCC[1]

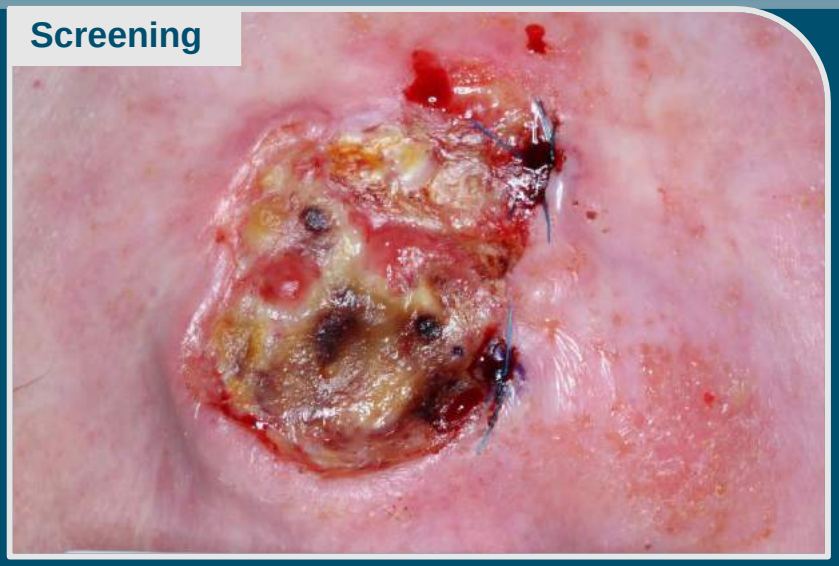


Right Cranial Lesion

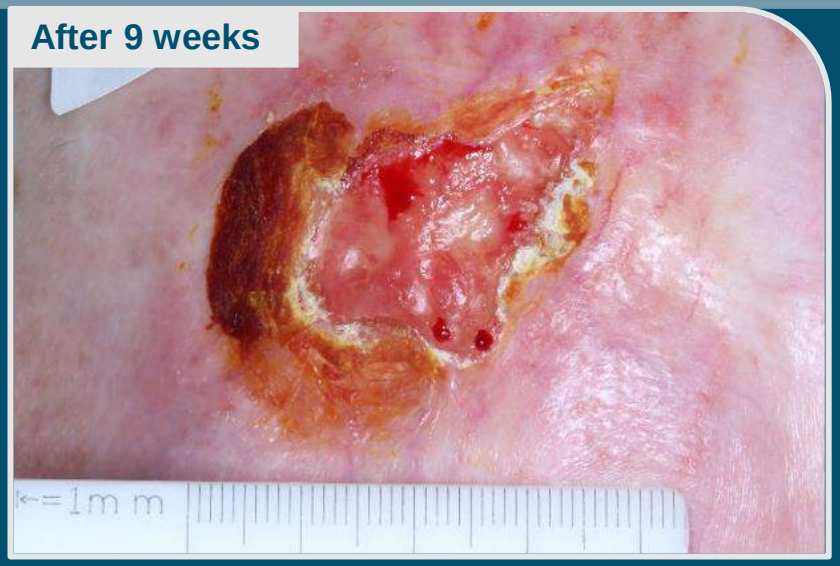
This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[2] Individual patient responses may vary.

ORR in Study 1620 was 32% in patients with laBCC; median DOR was not reached (range: 2.1-36.8+ months)[2]

Screening



After 9 weeks



After 101 weeks

Patient discontinued prior vismodegib due to intolerance

Clinical outcomes (data cutoff 5/20/2021[1])

Best response: Partial response* | **Time to response:** 2.1 months | **Duration of response:** 29.9+ months

Plus sign (+) denotes ongoing at last assessment.

*Per composite (RECIST 1.1 and WHO Criteria). Actual clinical trial patient.

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

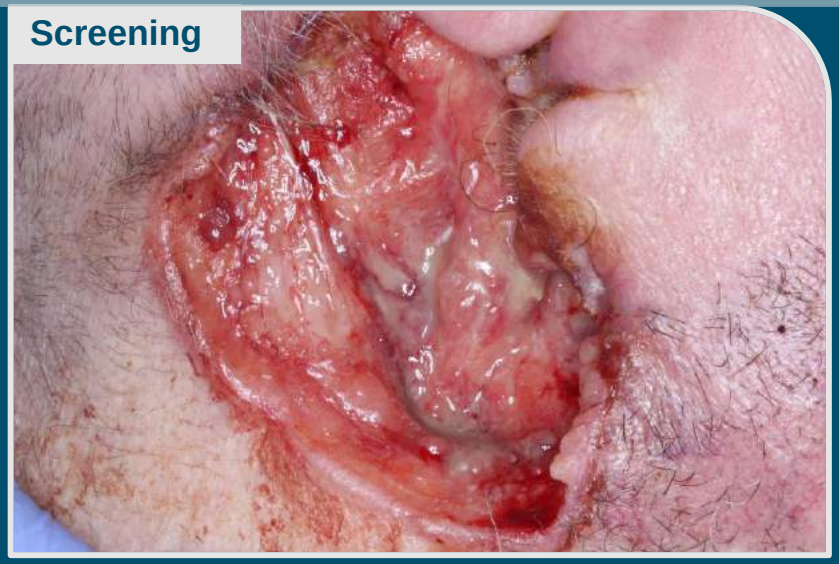
CASE STUDY 2

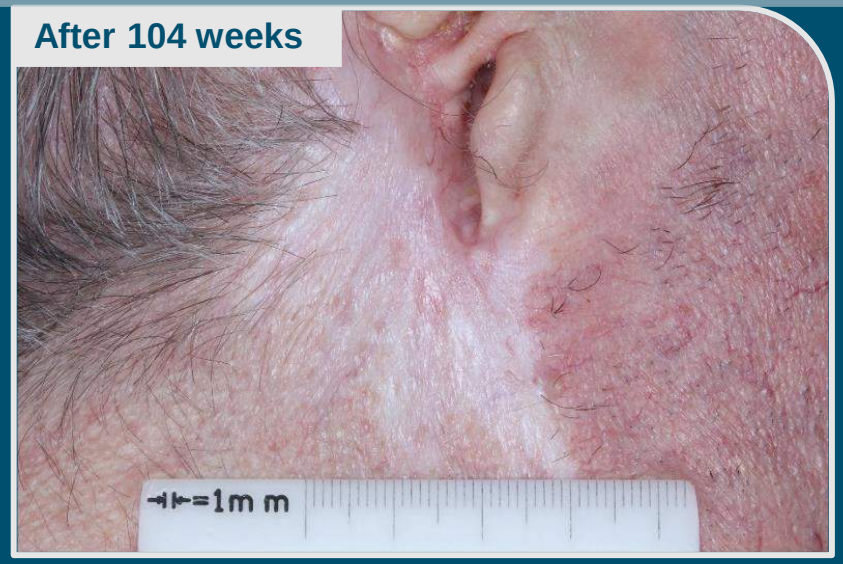
79-Year-Old Patient with Locally Advanced BCC[1]

Right Auricular Lesion

This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[2] Individual patient responses may vary.

ORR in Study 1620 was 32% in patients with laBCC; median DOR was not reached (range: 2.1-36.8+ months)[2]





Patient discontinued prior vismodegib due to disease progression

Clinical outcomes (data cutoff 5/20/2021[1])

Best response: Partial response* | **Time to response:** 4.2 months | **Duration of response:** 32.4+ months

Plus sign (+) denotes ongoing at last assessment.

*Per composite (RECIST 1.1 and WHO Criteria). Actual clinical trial patient.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Important Safety Information (Cont.)

Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

Immune-mediated pneumonitis

LIBTAYO can cause immune-mediated pneumonitis

In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation

Immune-mediated pneumonitis occurred in 2.6% (33/1281) of patients receiving LIBTAYO, including
- **Grade 4 (0.3%)**
- **Grade 3 (0.6%)**
- **Grade 2 (1.6%)**

Pneumonitis led to **permanent discontinuation in**	Pneumonitis led to **withholding of LIBTAYO in**
1.3% of patients	**1.4% of patients**

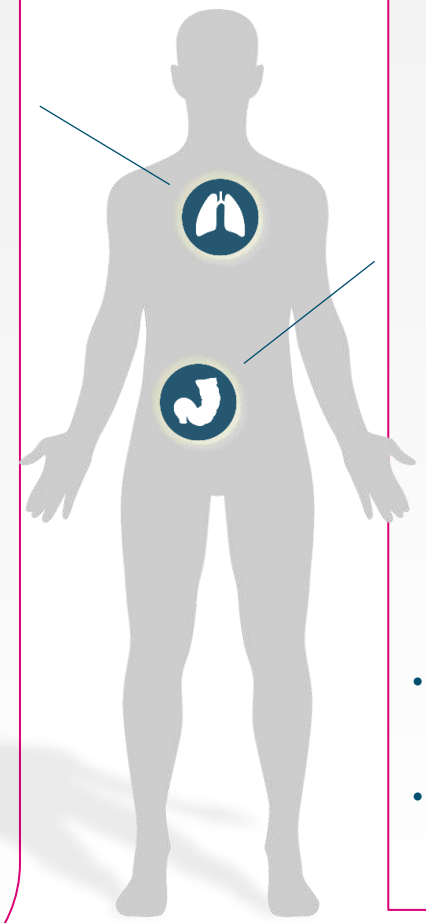
Systemic corticosteroids were required in all patients with pneumonitis

Pneumonitis resolved in 61% of the 33 patients

Of the 18 patients in whom LIBTAYO was withheld, **10 reinitiated after symptom improvement; of these, 4/10 (40%) had recurrence of pneumonitis**

- **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 <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% (25/1281) of patients receiving LIBTAYO, including
- **Grade 3 (0.8%)**
- **Grade 2 (0.9%)**

Colitis led to **permanent discontinuation in**	Colitis led to **withholding of LIBTAYO in**
0.4% of patients	**1.2% of patients**

Systemic corticosteroids were required in all patients with colitis

Colitis resolved in 56% of the 25 patients

Of the 16 patients in whom LIBTAYO was withheld, **6 reinitiated LIBTAYO after symptom improvement; of these, 4/6 (67%) had recurrence**

- **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 <10 mg per day (or equivalent) within 12 weeks of initiating steroids

Please see additional Important Safety Information throughout and full Prescribing Information available at this presentation.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

Important Safety Information (Cont.)

Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

Immune-mediated hepatitis

LIBTAYO can cause immune-mediated hepatitis

Immune-mediated hepatitis occurred in 2.4% (31/1281) of patients receiving LIBTAYO, including

- **Fatal (<0.1%)**
- **Grade 4 (0.3%)**
- **Grade 3 (1.6%)**
- **Grade 2 (0.2%)**

Hepatitis led to permanent discontinuation of LIBTAYO in **1.4% of patients**

Hepatitis led to withholding of LIBTAYO in **0.7% of patients**

Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 13% (4/31) of these patients

Hepatitis resolved in 39% of the 31 patients

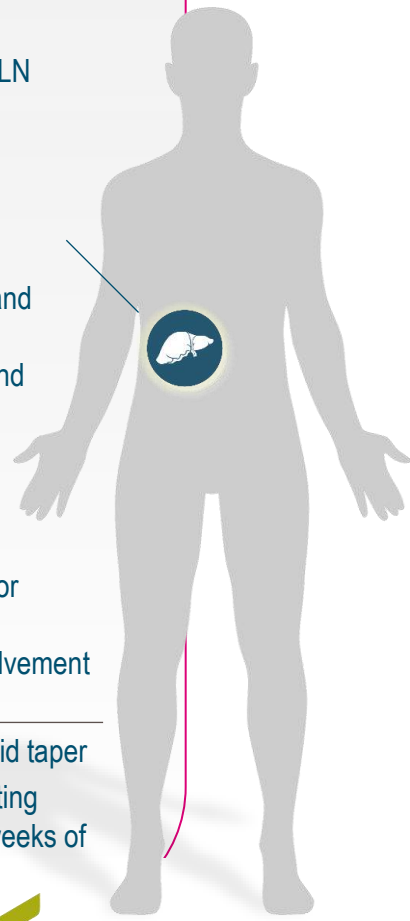
Of the 9 patients in whom LIBTAYO was withheld, **5 reinitiated LIBTAYO after symptom improvement; of these, 1/5 (20%) had recurrence**

For hepatitis with no tumor involvement of the liver

- **Withhold LIBTAYO if:**
  - AST or ALT increases to >3x and ≤8x ULN
  - Total bilirubin increases to >1.5x and ≤3x ULN
- **Permanently discontinue LIBTAYO if:**
  - AST or ALT increases to >8x ULN, or
  - Total bilirubin increases to >3x ULN

For hepatitis with tumor involvement of the liver

- **Withhold LIBTAYO if:**
  - Baseline AST or ALT is >1x and ≤3x ULN, and increases to >5x and ≤10x ULN
  - Baseline AST or ALT is >3x and ≤5x ULN and increases to >8x and ≤10x ULN
- **Permanently discontinue LIBTAYO if**
  - AST or ALT increases to >10x ULN, or
  - Total bilirubin increases to >3x ULN
- If AST and ALT are ≤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 <10 mg per day (or equivalent) within 12 weeks of initiating steroids

Please see additional Important Safety Information throughout and full Prescribing Information available at this presentation.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

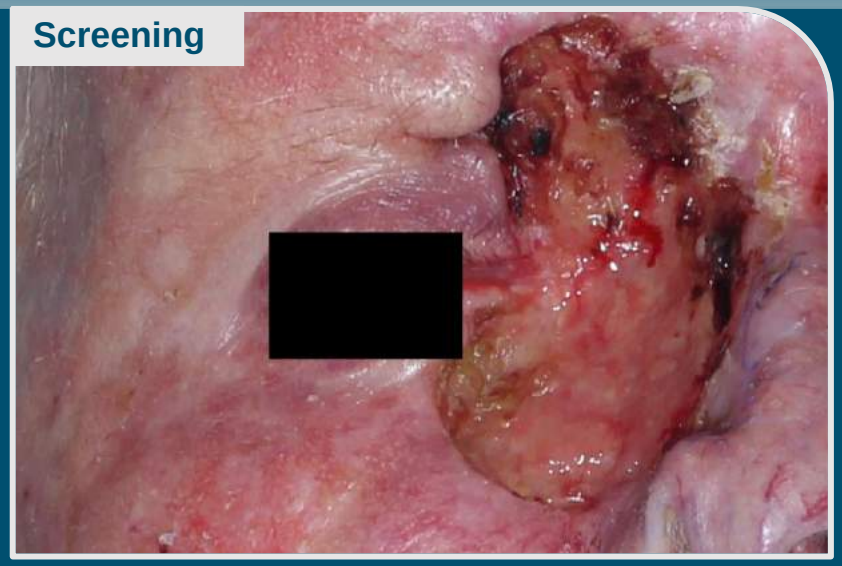
CASE STUDY 3

77-Year-Old Patient with Locally Advanced BCC[1]

Right Nasal Cavity Lesion

This is an example from the 25% of patients with laBCC who had a PR in Study 1620.[2] Individual patient responses may vary.

ORR in Study 1620 was 32% in patients with laBCC; median DOR was not reached (range: 2.1-36.8+ months)[2]



Patient discontinued prior vismodegib due to disease progression

Clinical outcomes (data cutoff 5/20/2021[1])

Best response: Partial response* | **Time to response:** 8.2 months | **Duration of response:** 4.8 months

At the time of data cutoff, this patient was no longer in response due to having progressive disease

Plus sign (+) denotes ongoing at last assessment.

*Per composite (RECIST 1.1 and WHO Criteria). Actual clinical trial patient.

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

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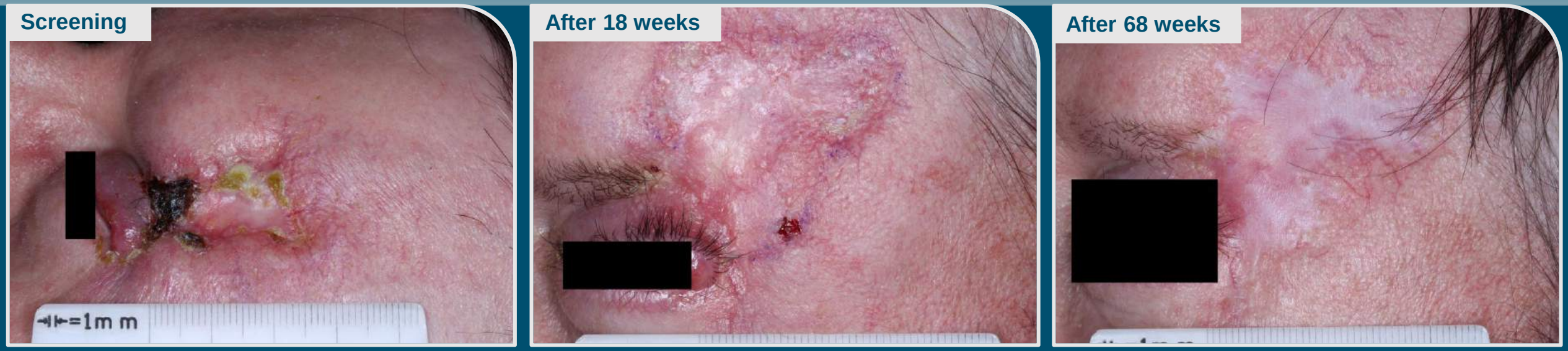
CASE STUDY 4

49-Year-Old Patient with Locally Advanced BCC[1]

Left Periorbital Lesion

This is an example from the 7% of patients with laBCC who had a CR in Study 1620.[2] Individual patient responses may vary.

ORR in Study 1620 was 32% in patients with laBCC; median DOR was not reached (range: 2.1-36.8+ months)[2]



Patient discontinued prior vismodegib due to disease progression

Clinical outcomes (data cutoff 5/20/2021[1])

Best response: Complete response* | **Time to response:** 4.2 months | **Duration of response:** 23.8+ months

Plus sign (+) denotes ongoing at last assessment.

*Per composite (RECIST 1.1 and WHO Criteria). Actual clinical trial patient.

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Important Safety Information (Cont.)

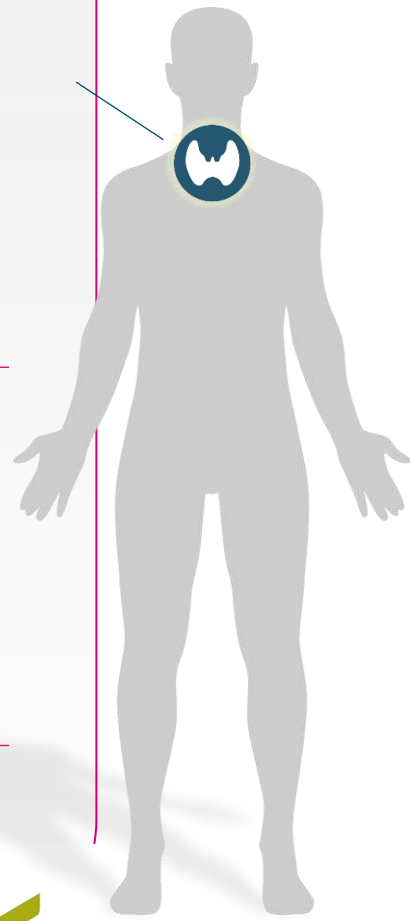
Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

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% (6/1281) of patients receiving LIBTAYO, including Grade 3 (0.5%). Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient. LIBTAYO was withheld in 1 (<0.1%) patient due to adrenal insufficiency and not reinitiated. Systemic corticosteroids were required in 83% (5/6) patients with adrenal insufficiency; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency had resolved in 17% of the 6 patients
Hypophysitis LIBTAYO can cause immune-mediated hypophysitis	Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue depending on severity. Hypophysitis occurred in 0.5% (7/1281) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.3%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient and withholding of LIBTAYO in 2 (0.2%) patients. Systemic corticosteroids were required in 86% (6/7) of patients with hypophysitis. Hypophysitis resolved in 14% of the 7 patients. Of the 2 patients in whom LIBTAYO was withheld for hypophysitis, none of the patients reinitiated
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



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Injection 350 mg

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Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

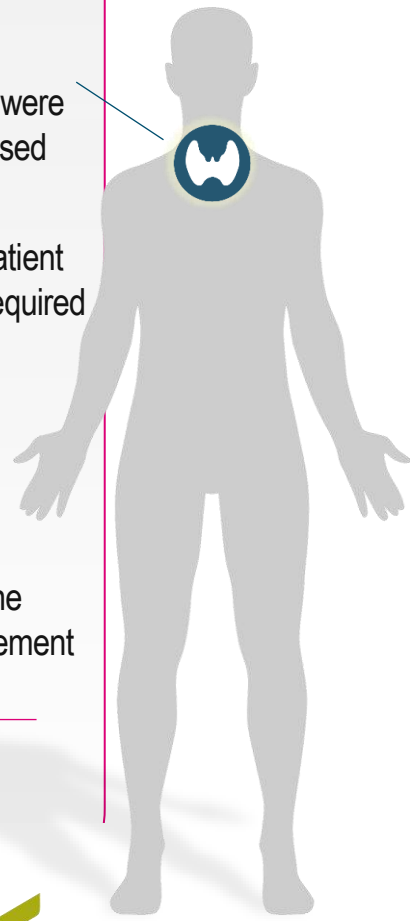
Important Safety Information (Cont.)

Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

Immune-mediated endocrinopathies (Cont.)

Thyroiditis	Thyroiditis occurred in 0.6% (8/1281) of patients receiving LIBTAYO, including Grade 2 (0.3%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 (<0.1%) patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis resolved in 13% of the 8 patients. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported
Hyperthyroidism	Hyperthyroidism occurred in 3% (39/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 7 (0.5%) patients due to hyperthyroidism. Systemic corticosteroids were required in 8% (3/39) of patients. Hyperthyroidism resolved in 56% of 39 patients. Of the 7 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism
Hypothyroidism	Hypothyroidism occurred in 7% (87/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 3 (0.2%) patients. Hypothyroidism led to withholding of LIBTAYO in 9 (0.7%) patients. Systemic corticosteroids were required in 1.1% (1/87) of patients with hypothyroidism. Hypothyroidism resolved in 6% of the 87 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement and did not have recurrence of hypothyroidism
Type 1 diabetes mellitus, which can present with diabetic ketoacidosis	Monitor for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBTAYO depending on severity. Type 1 diabetes mellitus occurred in <0.1% (1/1281) of patients (Grade 4). No patient discontinued treatment due to Type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients, treatment was reinitiated after symptom improvement. Patient received long-term insulin therapy



LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

LIBTAYO Has Straightforward Dosing

No PD-L1 or TMB testing is required before starting LIBTAYO in advanced BCC or advanced CSCC

A fixed 350-mg dose from a single-dose vial

An IV infusion for 30 minutes

Every 3 weeks

Treatment is to be continued until disease progression, unacceptable toxicity, or up to 24 months

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

IV, intravenous.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Important Safety Information (Cont.)

Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

Immune-mediated nephritis with renal dysfunction

LIBTAYO can cause immune-mediated nephritis

Immune-mediated nephritis occurred in
0.7% (9/1281) of patients
receiving LIBTAYO, including
- **Fatal (<0.1%)**
- **Grade 3 (<0.1%)**
- **Grade 2 (0.5%)**

Nephritis led to **permanent discontinuation in**	Nephritis led to **withholding of LIBTAYO in**
0.2% of patients	**0.4% of patients**

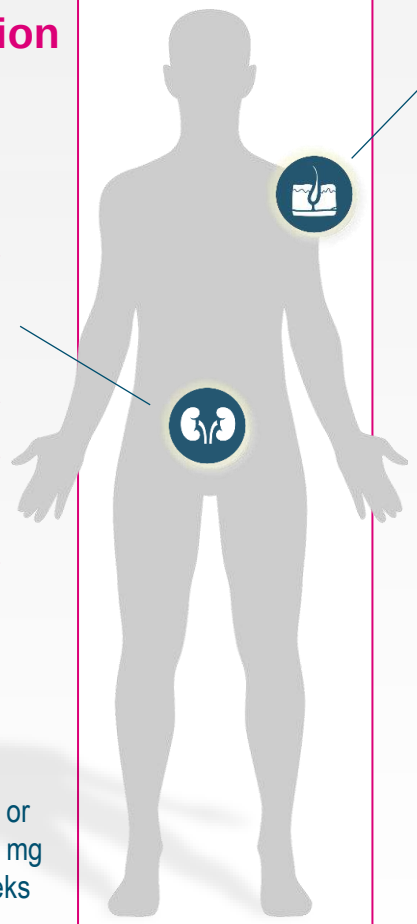
Systemic corticosteroids were required in all patients with nephritis

Nephritis resolved in
78% of the 9 patients

Of the 5 patients in whom LIBTAYO was withheld,
4 reinitiated LIBTAYO after symptom improvement;
of these, 1/4 (25%) had recurrence

- **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 <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
1.9% (24/1281) of patients
receiving LIBTAYO, including
- **Grade 3 (0.9%)**
- **Grade 2 (0.8%)**

Immune-mediated dermatologic adverse reactions led to

permanent discontinuation in	**withholding of LIBTAYO in**
0.2% of patients	**1.3% of patients**

Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions

Immune-mediated dermatologic adverse reactions resolved in
71% of the 24 patients

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

- **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 <10 mg per day (or equivalent) within 12 weeks of initiating steroids

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

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FPO:
Speaker
Image

What is the infusion process like for you?

What has your medical team discussed with you regarding your treatment?

How has your experience with LIBTAYO been so far?

QUESTION & ANSWER

SESSION

LIBTAYO Surround® Helps Eligible Patients Access LIBTAYO and Navigate the Insurance Process

LIBTAYO Surround can help support patients throughout their treatment journey

Financial Support

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

- **Commercial Copay Program**
- **Patient Assistance Program**

Access and Reimbursement Support

Support to help patients receive their medication as quickly as possible, including:

- **Benefits investigation**
- **Prior authorization and appeal assistance**
- **Claims assistance for billing and reimbursement**
- **Product support**

Additional LIBTAYO Surround Support

Support from our dedicated Patient Navigators, who are available to complement the support provided by HCPs once they are prescribed LIBTAYO

LIBTAYO SURROUND®

Visit LIBTAYOSurround.com or view QR code to learn more

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

HCP, healthcare professional.

Reference: Data on file. Regeneron Pharmaceuticals, Inc.

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Educational Resources Are Available for Patients Receiving LIBTAYO, Caregivers, and Healthcare Professionals

Patient Brochures

Information for patients with advanced BCC or advanced CSCC and their caregivers, available in multiple languages

LIBTAYO Starter Kit

Resources and tools available for patients beginning their LIBTAYO treatment journey

Formulary Kit

Resources to assist healthcare professionals in evaluating LIBTAYO

Speak to a representative or visit libtayohcp.com to learn more about available resources for you and your patients

Please see Important Safety Information throughout and full Prescribing Information available at this presentation.

Reference: Data on file. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Important Safety Information (Cont.)

Warnings and Precautions (Cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (Cont.)

Other immune-mediated adverse reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 1281 patients who received LIBTAYO or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions

Cardiac/vascular: Myocarditis, pericarditis, and vasculitis. Permanently discontinue for Grades 2, 3, or 4 myocarditis

Nervous system: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy. 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

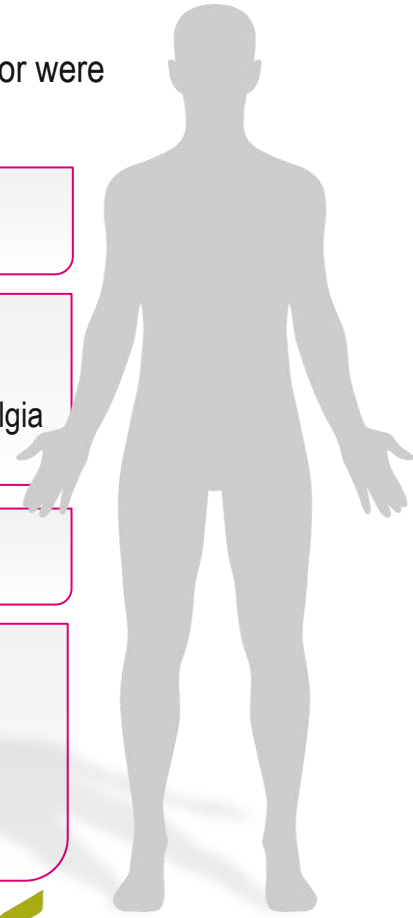
Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like 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/dermatomyositis, 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 thrombocytopenia, solid organ transplant rejection



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Important Safety Information (Cont.)

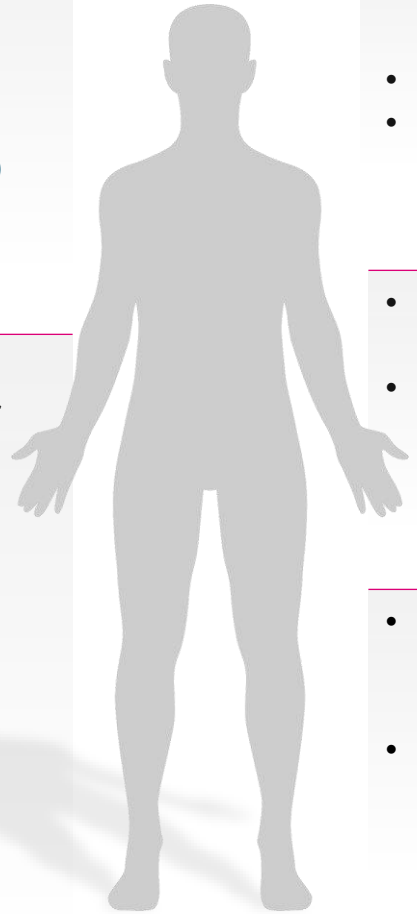
Warnings and Precautions (Cont.)

Infusion-Related Reactions

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

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

- *LIBTAYO as a single agent*: the most common adverse reactions (≥15%) are fatigue, musculoskeletal pain, rash, diarrhea, and anemia
- *LIBTAYO in combination with platinum-based chemotherapy*: the most common adverse reactions (≥15%) are alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite

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 full Prescribing Information available at this presentation.

Reference: LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

FPO:
Speaker
Image

What has been helpful for your treatment journey?

Have you had an opportunity to meet other people living with advanced BCC?

QUESTION & ANSWER SESSION

Program Summary

In the management of patients with aBCC and aCSCC, **guidelines recommend a multidisciplinary team approach**[1,2]

Multidisciplinary teams can help evaluate treatment options and manage care for patients with aBCC and aCSCC

LIBTAYO is the **first and only** treatment indicated for patients with laBCC or mBCC who have been previously treated with an HHI or for whom an HHI is not appropriate[3]

LIBTAYO offers >8 years of clinical treatment experience[3,4,*]

#1 LIBTAYO is the most prescribed immunotherapy by oncologists for patients across both advanced BCC and advanced CSCC[3,5,†]

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 available at this presentation.

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

†Estimate based on IQVIA medical claims data from October 2018 through May 2023 and calibrated with actual vials sold.[5]

References: 1. Alam M, et al. *J Am Acad Dermatol*. 2018;78(3):560-578. **2.** Bichakjian C, et al. *J Am Acad Dermatol*. 2018;78(3):540-559. **3.** LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **4.** Study of REGN2810 (anti-PD-1) in patients with advanced malignancies. ClinicalTrials.gov. Updated January 27, 2020. Accessed March 22, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT02383212. **5.** Data on file. Regeneron Pharmaceuticals, Inc.

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

Thank you for attending!

"We are not survivors, but WARRIORS…we fight every day!"

- Donna