BALANCE THAT MATTERS

UNLOXCYT™ is an evolution in checkpoint inhibition for the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.[1-4]

Not an actual patient.

UNLOXCYT offers a balanced treatment approach[1-4]:

Many patients experienced durable efficacy[1,2]

- ≥50% of patients receiving UNLOXCYT achieved an objective response; median DOR not yet reached for either group

UNLOXCYT has a proven tolerability profile[1]

- The most common adverse reactions were fatigue, musculoskeletal pain, rash, diarrhea, and hypothyroidism
- imARs were primarily Grade 1 or 2; 0.9% were Grade 3 (dermatologic only), with no Grade ≥4 imARs

Multifaceted MOA of UNLOXCYT[1-4,*]

The **first and only** checkpoint inhibitor in aCSCC that helps restore the adaptive immune response and engage the innate immune system while preserving PD-L2 signaling[1-6]

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); DOR=duration of response; imAR=immune-mediated adverse reaction; MOA=mechanism of action; PD-L2=programmed death-ligand 2.

*The MOA of UNLOXCYT is based on in vitro data. Preclinical in vitro data may not translate to clinical outcomes.[1,7]

Next

It is not known if UNLOXCYT is safe and effective in children.

The recommended dosage of UNLOXCYT is 1200 mg as an intravenous infusion over 60 minutes every 3 weeks.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Thousands progress to aCSCC annually and many are elderly with comorbidities[8-13]

40,000+ people

progress to nodal metastasis each year[8,9]

~15,000 people

die of aCSCC annually[9]

Many patients are also managing other health concerns[10-13]

~70 **The average age at diagnosis is ~70 years.**[10]

Comorbidities are common—such as hypertension, diabetes, kidney disease, and respiratory disease[11,12]

Many aCSCC patients are immunocompromised—some may have undergone an organ transplant and are receiving immunosuppressants[13]

Real-world patients may differ from clinical trial participants, commonly presenting with reduced performance status, significant comorbidities, and socioeconomic barriers that may not be fully represented in clinical studies.[14,15]

MANY aCSCC PATIENTS RECEIVE IMMUNOTHERAPY.[1,16] BASED ON MULTIPLE REAL-WORLD ANALYSES, GRADE ≥3 imARs MAY BE EXPERIENCED BY ~14% TO 36% OF PATIENTS[17,18,*]

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); imAR=immune-mediated adverse reaction.

*Results derived from real-world analyses are not directly comparable to outcomes observed in controlled clinical trial settings.

Previous Next

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT™.

UNLOXCYT™ offers a balanced treatment approach for your aCSCC patients[1,2,4]

UNLOXCYT demonstrated durable efficacy and a proven tolerability profile in aCSCC[1,2]

The pivotal study had comparable size and patient population to other studies of checkpoint inhibitors in aCSCC.[1,2,5,6]

Durable Efficacy (N=109)[1]

Met primary endpoint in both patient populations[1,2]	
mCSCC (50% ORR)	laCSCC (55% ORR)
Most respondents were still in response at 1 year[1,*]	
mCSCC (67%)	laCSCC (88%)

Proven Tolerability[1]

- The most common adverse reactions were fatigue, musculoskeletal pain, rash, diarrhea, and hypothyroidism (N=141)[1]
- imARs were primarily Grade 1 or 2; 0.9% were Grade 3 (dermatologic only), with no Grade ≥4 imARs (N=223; 141 aCSCC patients, 82 patients with other cancers[†])[1]
- 8% permanent discontinuation rate (N=141 aCSCC patients)[1]

UNLOXCYT has a multifaceted MOA[1-4,‡]

The first and only checkpoint inhibitor in aCSCC that helps restore the adaptive immune response and engage the innate immune system while preserving PD-L2 signaling.[1-6]

Mechanisms of Action[‡]	UNLOXCYT	PD-1 Inhibitors
Binds to PD-L1 on tumor cells, preventing the interaction with PD-1 on T cells, which activates adaptive immune function and enables T cells to recognize cancer cells[1-3,5,6]	YES	NO
Binds to PD-1 on T cells, preventing the interaction with PD-L1 on tumor cells, which activates adaptive immune function and enables T cells to recognize cancer cells[1-3,5,6]	NO	YES
Preserves PD-L2 signaling. This may help maintain some immune tolerance in non-tumor tissues, such as the lung and liver, reducing off-target effects and immune-mediated adverse reactions[1-6]	YES	NO
Binds to PD-L1 on tumor cells, preventing the interaction with B7.1 on antigen-presenting cells, which allows B7.1 to engage with CD28 on T cells as part of the adaptive immune response[1,2,4-6]	YES	NO
Through an active Fc fragment, binds to NK cells to induce antibody-dependent cellular cytotoxicity (ADCC)[1-3,5,6]	YES	NO

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); B7.1=B7, type 1 membrane protein (also called CD80); CD=cluster of differentiation; Fc=fragment crystallizable; imAR=immune-mediated adverse reaction; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; MOA=mechanism of action; NK=natural killer; ORR=objective response rate; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1; PD-L2=programmed death-ligand 2.

*The numerator includes the number of patients whose observed DOR reached at least the specified time of 12 months. Patients who did not have the opportunity to reach the specified timepoint were included in the denominator only.[1]

[†]Other tumors were solid tumors and hematologic malignancies.[1]

[‡]The MOA of UNLOXCYT is based on in vitro data. Preclinical in vitro data may not translate to clinical outcomes.[1,7]

IMPORTANT SAFETY INFORMATION

WARNING AND PRECAUTIONS

Immune-mediated Adverse Reactions:

Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, nephritis and renal dysfunction, and solid organ transplant rejection.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

The efficacy and safety of UNLOXCYT™ was evaluated in a multicenter, multicohort, open-label study of aCSCC patients, including many with comorbidities[1,2,19]

Study Design[1,2]

mCSCC patients (n=78)
UNLOXCYT 800 mg Q2W administered as an IV infusion

laCSCC patients who were not candidates for curative surgery or radiation (n=31)
UNLOXCYT 800 mg Q2W administered as an IV infusion

Endpoints[1,2]

PRIMARY
- ORR*

SECONDARY
- DOR*
- Incidence and severity of TEAEs†

Responders with observed DOR were assessed at 6 months and 12 months

Patients received UNLOXCYT until disease progression or unacceptable toxicity.[1]

Baseline demographics[1]

The efficacy population consisted of 109 patients with either mCSCC or laCSCC:

- Median age was 75 years (range: 37-95)
- 66% had ECOG PS of 1
- 66% had prior surgery
- 69% had prior radiotherapy
- 7% received at least one prior anti-cancer systemic therapy

Many patients within the trial had other comorbidities[19]

In the safety population (N=141), 56.7% had hypertension, 11.3% had dyslipidemia or hypercholesterolemia, 10.6% had type 2 diabetes mellitus, 9.2% had coronary artery disease, 7.8% had depression, 5.7% had chronic kidney disease, and 2.1% had COPD.‡

Patients were excluded if they had active or suspected autoimmune disease, prior treatment with immune checkpoint inhibitors, allogeneic transplant within 6 months prior to treatment, uncontrolled or significant cardiovascular disease, ECOG PS ≥2, or infection with HIV, hepatitis B, or hepatitis C.[1]

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); COPD=chronic obstructive pulmonary disease; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group performance status; HIV=human immunodeficiency virus; ICR=independent central review; IV=intravenous; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; ORR=objective response rate; Q2W=every 2 weeks; RECIST=Response Evaluation Criteria in Solid Tumors; TEAE=treatment-emergent adverse event; WHO=World Health Organization.

*Evaluated by ICR per RECIST v1.1. For patients with laCSCC with lesions not assessable by radiologic imaging, ORR was determined by ICR assessment per WHO criteria by digital photography.[1,2,20]

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

‡Not a full list of comorbidities in patients included in the trial.[19]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

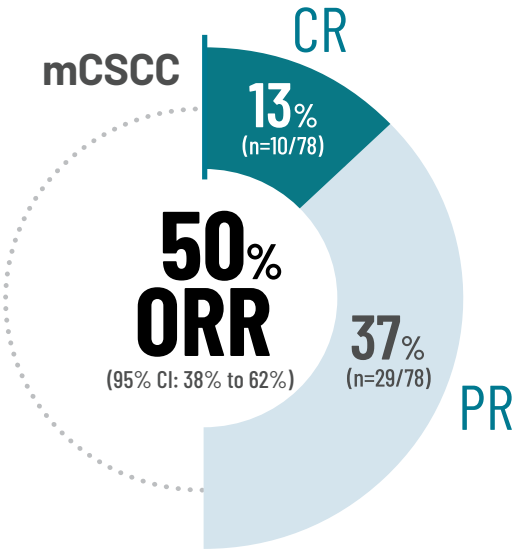
Immune-mediated Adverse Reactions (cont'd):

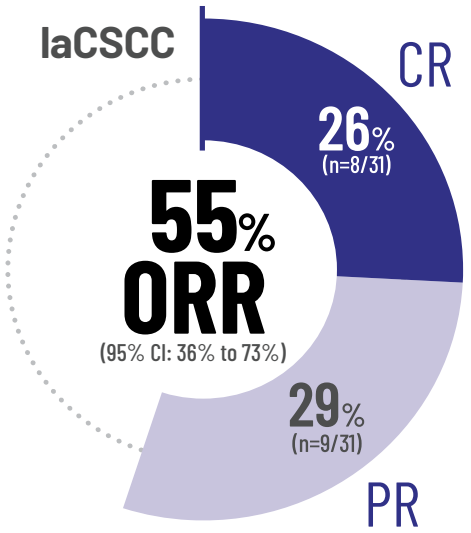
Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. While such adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1–blocking antibodies.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

≥50% of patients receiving UNLOXCYT™ achieved an objective response[1,2,*]

Primary Endpoint: ORR[1,2,*]





The median time to response was <4 months[2]

mCSCC: 1.9 months (range: 1.6-16.9)

laCSCC: 3.6 months (range: 1.7-10.1)

CI=confidence interval; CR=complete response; ICR=independent central review; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; ORR=objective response rate; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; WHO=World Health Organization.

*Evaluated by ICR per RECIST v1.1. For patients with laCSCC with lesions not assessable by radiologic imaging, ORR was determined by ICR assessment per WHO criteria by digital photography.[1,2]

IMPORTANT SAFETY INFORMATION (cont'd)

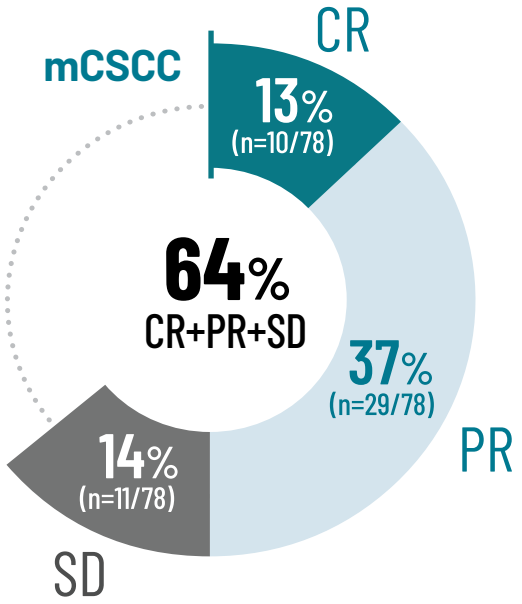
WARNING AND PRECAUTIONS (cont'd)

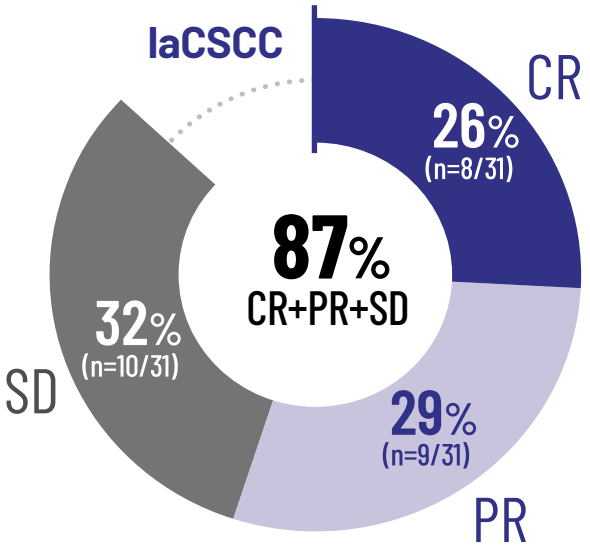
Immune-mediated Adverse Reactions (cont'd):
Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue UNLOXCYT based on the severity of reaction.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

UNLOXCYT™ helped achieve disease control in both mCSCC and laCSCC patients[2]

Patients achieved disease control with UNLOXCYT, including patients who demonstrated stable disease[2,21,*]





laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; SD=stable disease.

*SD is defined as neither sufficient tumor shrinkage to qualify for PR nor sufficient tumor increase to qualify for progressive disease.[20]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

Infusion-Related Reactions:

Infusion-related reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue UNLOXCYT based on severity of reaction.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Patients receiving UNLOXCYT™ also experienced durable responses[1]

Secondary Endpoint: DOR[1,20,*]

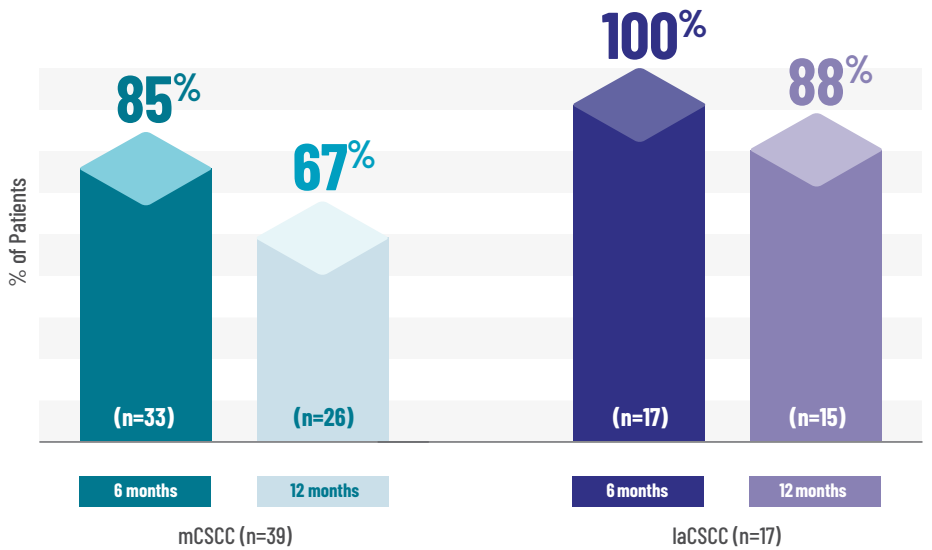
The majority of patients who responded to treatment sustained response at 1 year[1]

The median DOR was not reached in either group[1,*,†]

mCSCC: NR (range: 1.4+–45.3+ months)

laCSCC: NR (range: 8.3–31.3+ months)

PATIENTS WITH AN ONGOING RESPONSE AT 6 MONTHS AND 12 MONTHS[1,*,‡,§]



DOR=duration of response; ICR=independent central review; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; NR=not reached; RECIST=Response Evaluation Criteria in Solid Tumors.

*Evaluated by ICR per RECIST v1.1.[1,20]

†Based on Kaplan-Meier estimate.[1]

‡Median follow-up time was 29.3 months for mCSCC and 24.1 months for laCSCC.[1]

§The numerator includes the number of patients whose observed DOR reached at least the specified times of 6 months or 12 months. Patients who did not have the opportunity to reach the specified timepoint were included in the denominator only.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

Infusion-Related Reactions (cont'd):

Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Patients receiving UNLOXCYT™ experienced a low incidence of Grade ≥3 imARs[1]

UNLOXCYT patients experienced few Grade 3 and no Grade 4 or 5 imARs[1]

Based on the pooled safety population of 223 patients treated with UNLOXCYT[1,*]:

Two Grade 3 imARs (both dermatologic reactions) were reported[1]

0.9%

There were no reported Grade ≥4 imARs[1]

0.0%

~24% of patients (N=223) in the UNLOXCYT clinical trials experienced Grade 1 or Grade 2 imARs[1,*,†]

- Pneumonitis was reported in 1% of patients; all were Grade 2[1]
- Dermatologic events were reported in 7% of patients (4% Grade 2, 0.9% Grade 3)[1]
- Grade 1 or Grade 2 imARs were: colitis (0.4%), adrenal insufficiency (0.9%), hypothyroidism (10%), and hyperthyroidism (5%)[1]

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); imAR=immune-mediated adverse reaction.

*Patients treated with UNLOXCYT as a single agent across two multicohort, open-label studies: 141 patients with aCSCC and 82 with other solid tumors and hematologic malignancies.[1]

†<1% of patients experienced clinically significant imARs involving each of the following systems: cardiac/vascular, nervous system, ocular, gastrointestinal, musculoskeletal and connective tissue, endocrine, or hematologic/immune.[1]

Previous Next

Please see Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Overall, UNLOXCYT™ has a proven tolerability profile[1]

The most common ARs were primarily Grade 1 or 2—rarely Grade 3 or 4[1]

ARs in ≥10% of Patients[1,*]

		UNLOXCYT N=141	
System Organ Class	**Preferred Term**	**All Grades (%)**	**Grades 3 or 4 (%)**
General disorders and administrative site conditions	Fatigue†	33	3
	Edema†	11	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain†	25	3
Skin and subcutaneous tissue disorders	Rash†	23	1
	Pruritus†	12	0
Endocrine disorder	Hypothyroidism†	14	0
Gastrointestinal disorders	Diarrhea	14	0
	Nausea	13	0
	Constipation	13	0
Nervous system disorders	Headache†	12	0
Infections and infestations	Localized infection	10	0.7
	Urinary tract infection†	10	0

31% of patients experienced serious ARs.[1]
The most frequent were sepsis (2.8%), pneumonia (2.8%), and pyrexia (2.1%).[1]

There were no treatment-related deaths.[2]

8% of patients permanently discontinued UNLOXCYT due to ARs.[1,‡]

The median duration of exposure was 36 weeks (2 weeks to 3.7 years) in the safety population of 141 patients.[1]

The most common ARs (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.[1]

AR=adverse reaction; COVID-19=coronavirus disease 2019; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

*Toxicity was graded per NCI CTCAE v.4.03 (or later version).[1]
†Represents a composite of multiple related terms.[1]
‡ARs resulting in permanent discontinuation of UNLOXCYT were COVID-19, COVID-19 pneumonia, sepsis, ulcerative keratitis, tumor thrombosis, axillary pain, paresthesia, cholestasis, hepatic cytolysis, wound hemorrhage, neck pain, pemphigoid, and eye pain (1 patient each).[1]

Please see Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

An evolution in checkpoint inhibition[1-4,*]

UNLOXCYT™ has a multifaceted MOA that helps restore the adaptive and engage the innate immune systems[1-4,*]

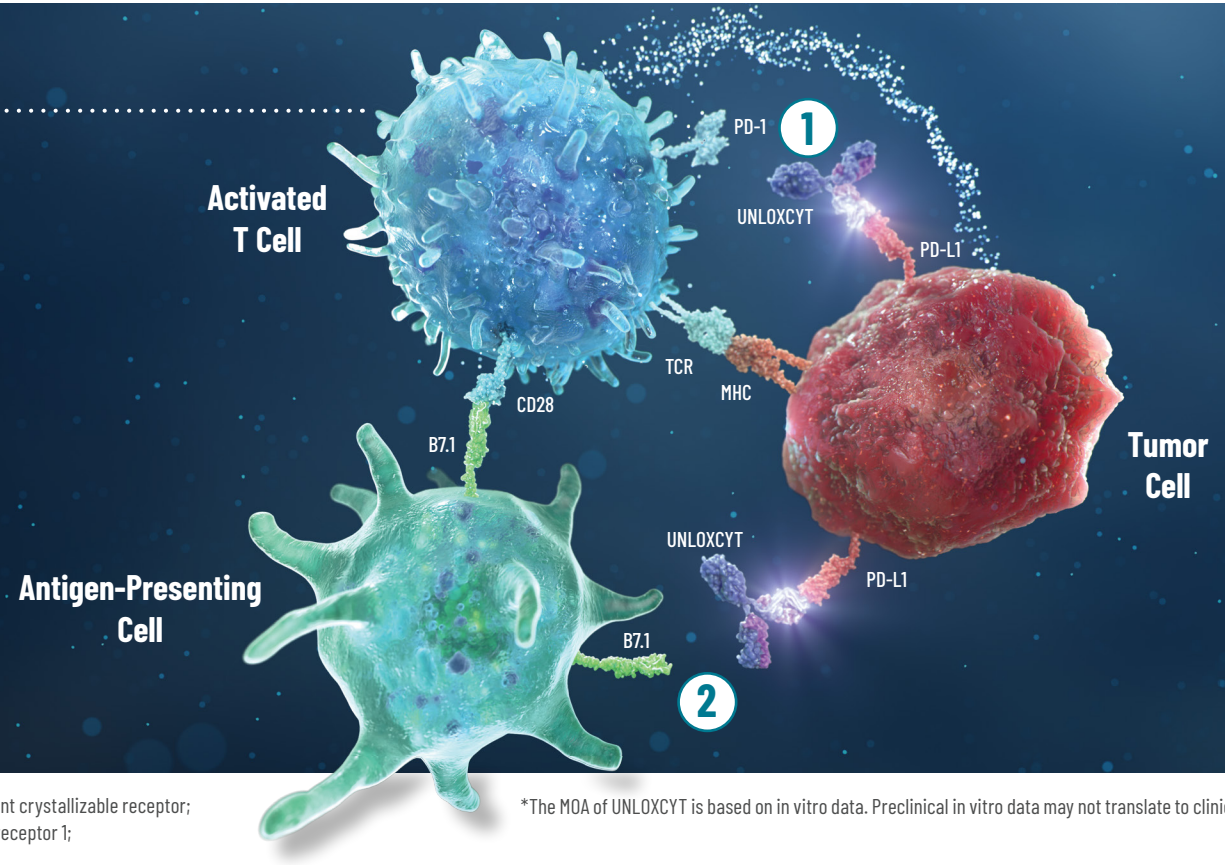
RESTORING ADAPTIVE IMMUNITY

1

UNLOXCYT binds to PD-L1, which prevents its interaction with PD-1 on T cells, activating the adaptive immune system and enabling T cells to recognize cancer cells.[1-3]

2

UNLOXCYT also works by preventing the interaction between PD-L1 and B7.1 on antigen-presenting cells, which allows B7.1 to engage with CD28 on T cells and reverses the inhibitory signals that dampen antitumor responses.[1,2,4]



B7.1=B7, type 1 membrane protein (also called CD80); CD=cluster of differentiation; FcR=fragment crystallizable receptor; MHC=major histocompatibility complex; MOA=mechanism of action; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1; TCR=T-cell receptor.

*The MOA of UNLOXCYT is based on in vitro data. Preclinical in vitro data may not translate to clinical outcomes.[1,7]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

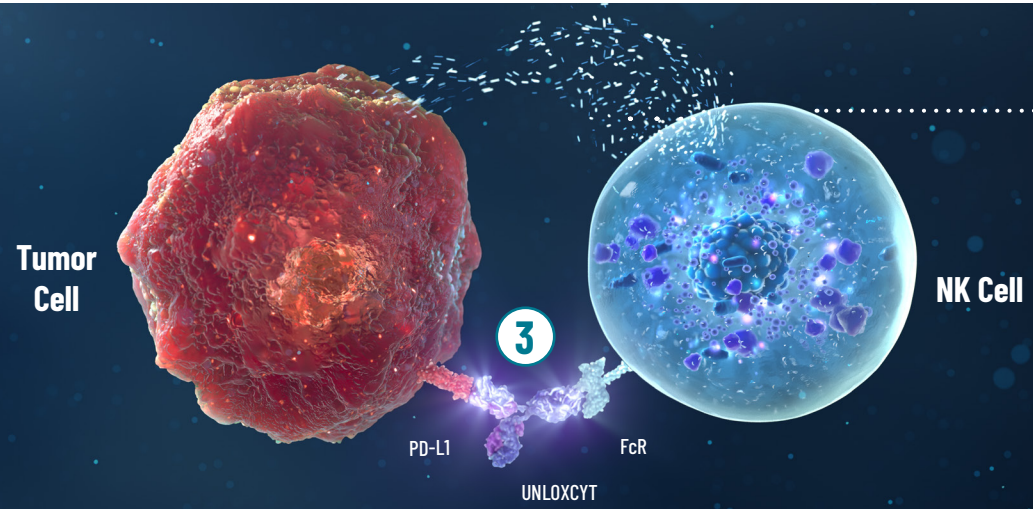
Complications of Allogeneic HSCT:

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/PDL1 blocking antibody.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

An evolution in checkpoint inhibition[1-4,*]

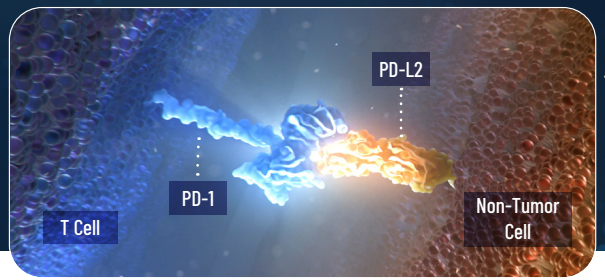
UNLOXCYT™ has a multifaceted MOA that helps restore the adaptive and engage the innate immune systems[1-4,*]



ENGAGING INNATE IMMUNITY

3

UNLOXCYT has a secondary MOA that rapidly engages innate immune function through an active Fc domain that binds with NK cells to induce antibody-dependent cellular cytotoxicity (ADCC).[1-3]



PRESERVES PD-L2 SIGNALING

Interaction of PD-1 and PD-L2 leads to decreased T-cell activity. Keeping this signaling intact may help maintain some immune tolerance in non-tumor tissues, such as the lung and liver—preserving vital balance, reducing off-target effects and imARs.[1-4]

Fc=fragment crystallizable; imAR=immune-mediated adverse reaction; MOA=mechanism of action; NK=natural killer; PD-1=programmed death-receptor 1; PD-L1=programmed death-ligand 1; PD-L2=programmed death-ligand 2.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

Complications of Allogeneic HSCT (cont'd):

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

How to administer UNLOXCYT™

The recommended dosage of UNLOXCYT is 1200 mg IV over 60 minutes every 3 weeks (Q3W)[1]

1200 mg
(4 x 300 mg vials)

60 minutes

Every 3 weeks

The UNLOXCYT administration schedule may coincide with patient follow-up visits and monitoring

Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.[1]

Dose modifications for adverse reactions[1]

- No dose reductions of UNLOXCYT are recommended
- In general, withhold UNLOXCYT for severe (Grade 3) imARs

Permanently discontinue for[1]:

- Life-threatening (Grade 4) imARs, **or**
- Recurrent severe (Grade 3) imARs or requiring systemic immunosuppressive treatment, **or**
- The inability to reduce corticosteroid dose to a prednisone equivalent of 10 mg or less per day within 12 weeks of initiating steroids

UNLOXCYT infusions can continue unless there is disease progression or unacceptable toxicity.[1]

PLEASE SEE THE FULL PRESCRIBING INFORMATION FOR RECOMMENDED DOSE MODIFICATIONS FOR ADVERSE REACTIONS.[1]

imAR=immune-mediated adverse reaction; IV=intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity/Females and Males of Reproductive Potential:

UNLOXCYT can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating UNLOXCYT. Females should use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

How to prepare UNLOXCYT™

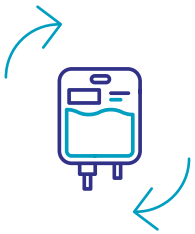
Steps to prepare and administer UNLOXCYT[1]:

Step 1

Add 20 mL (1200 mg; 4 x 300 mg vials) of UNLOXCYT to a 250 mL IV infusion bag containing 0.9% sodium chloride injection

Step 2

Mix diluted solution by gentle inversion. **Do not shake. Discard any unused portion left in the vial**



Step 3

Administer the contents over 60 minutes through an IV line. (**Do not** administer UNLOXCYT as an intravenous push or bolus injection **OR** co-administer other drugs through the same infusion line)

How to store UNLOXCYT[1]

The prepared solution may be stored either:

- At room temperature up to 77°F (25°C) for no more than 24 hours from the time of preparation until the end of the infusion
- Under refrigeration at 36°F to 46°F (2°C to 8°C) for no more than 24 hours from the time of preparation until the end of the infusion. If refrigerated, allow the diluted solution to reach room temperature prior to administration
- **Do not freeze**
- Discard after 24 hours

IV=intravenous.

All doses of UNLOXCYT should be inspected and properly prepared before administration. Before preparing UNLOXCYT for administration, inspect the medication first for particulate matter and discoloration. Discard the vial if any visible particles are observed.[1]

Do not shake the vial.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity/Females and Males of Reproductive Potential (cont'd):

Advise female patients not to breastfeed during treatment with UNLOXCYT and for 4 months after the last dose.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Case studies show 2 examples of complete response with UNLOXCYT™[1,2,22-25]

In the clinical trial, some patients achieved a complete response. These profiles are based on real patients with mCSCC or laCSCC[1,2,22-25]

Jeanette* postauricular skin lesion • mCSCC patient[22,24]

Jeanette is a 67-year-old retired kindergarten teacher with a medical history of chronic kidney disease, hypertension, and facial paralysis.[24]

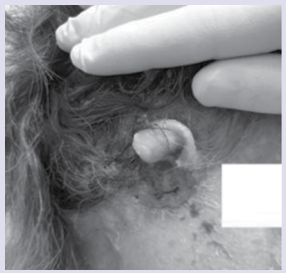
Initial diagnosis & treatment[24]

- First diagnosed with CSCC in August 2018
- Underwent surgical resection along with a parotidectomy
- Received adjuvant radiotherapy to her neck following surgery

Diagnosis of mCSCC[22,24]

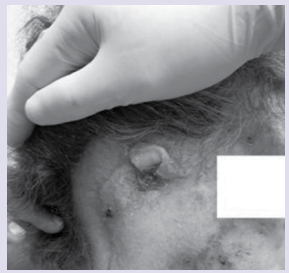
- Returned with a right postauricular skin lesion in 2019
- Diagnosed with mCSCC with metastases to the lung and skin
- Ineligible for curative surgery or radiotherapy due to:
  - Likelihood of recurrence
  - Metastasis of the cancer

Treatment with UNLOXCYT[22,24,25]

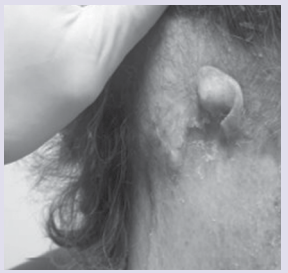


Screening: Baseline image at screening.

Initiated infusions of UNLOXCYT (800 mg Q2W).



Week 8: Notable improvement of lesion.



Week 26: Lesion continued to improve.

Complete response achieved by January 2022.

Adverse events

Fatigue and headache; resolved without medical intervention

CSCC=cutaneous squamous cell carcinoma; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; Q2W=every 2 weeks.

*Based on a real patient case developed in collaboration with a medical oncologist.[22] Patient name has been changed to protect her privacy.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Both cases had only mild to moderate side effects[23,24]

In the clinical trial, some patients achieved a complete response. These profiles are based on real patients with mCSCC or laCSCC[1,2,22-25]

Wilfred* facial skin lesion • laCSCC patient[23,24]

Wilfred is an 86-year-old retired construction worker with a medical history of diabetes, hypertension, and basal cell carcinoma.[24]

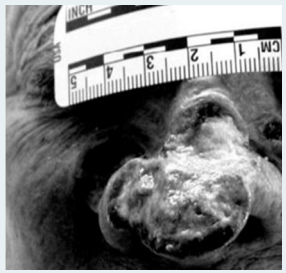
Initial diagnosis & treatment[24]

- Diagnosed with CSCC in April 2019
- Received multiple surgeries to remove lesions
- Had adjuvant radiotherapy to his nose following surgery

Diagnosis of laCSCC[24]

- Returned with a facial skin lesion in January 2021
- Diagnosed with laCSCC
- Ineligible for curative surgery or radiotherapy because:
  - Tumor had recurred after multiple prior surgeries
  - Cumulative dose limit was exceeded during prior radiotherapies

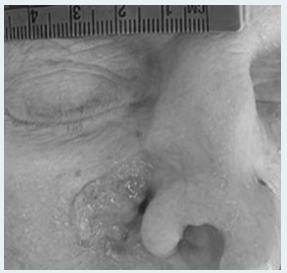
Treatment with UNLOXCYT™ 23-25



Screening: Baseline image at screening.

Initiated infusions of UNLOXCYT (800 mg Q2W).

Cycle 4: Visible reduction of lesion.



Cycle 11: Lesion continued to improve.

Complete response achieved by March 2024.

Adverse event

Rash; resolved without intervention

Images from Ruiz ES, *J Am Acad Dermatol*, 2026; (data appendix); legend and images revised. Licensed under Creative Commons International (CC International) BY 4.0.

CSCC=cutaneous squamous cell carcinoma; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; Q2W=every 2 weeks.

*Based on a real patient case developed in collaboration with a medical oncologist.[23] Patient name has been changed to protect his privacy.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

To report side effects of UNLOXCYT to FDA: visit www.fda.gov/medwatch or call 1-800-FDA-1088. Report SUSPECTED ADVERSE REACTIONS or any side effects or ADEs (adverse drug events) to our Drug Safety Department at 1-800-406-7984 or DrugSafety.USoperations@sunpharma.com (preferred) with as much information as available.

Please see additional Important Safety Information throughout and Full Prescribing Information for UNLOXCYT.

Important Safety Information

INDICATIONS AND USAGE

UNLOXCYT (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

It is not known if UNLOXCYT is safe and effective in children

The recommended dosage of UNLOXCYT is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks.

IMPORTANT SAFETY INFORMATION

WARNING AND PRECAUTIONS

Immune-mediated Adverse Reactions:
Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, nephritis and renal dysfunction, and solid organ transplant rejection. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. While such adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1–blocking antibodies.

Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue UNLOXCYT based on the severity of reaction.

Infusion-Related Reactions:
Infusion-related reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue UNLOXCYT based on severity of reaction. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

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/PDL1 blocking antibody. 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/Females and Males of Reproductive Potential:
UNLOXCYT can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating UNLOXCYT. Females should use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose. Advise female patients not to breastfeed during treatment with UNLOXCYT and for 4 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

To report side effects of UNLOXCYT to FDA: visit www.fda.gov/medwatch or call 1-800-FDA-1088. Report SUSPECTED ADVERSE REACTIONS or any side effects or ADEs (adverse drug events) to our Drug Safety Department at 1-800-406-7984 or DrugSafety.USoperations@sunpharma.com (preferred) with as much information as available.

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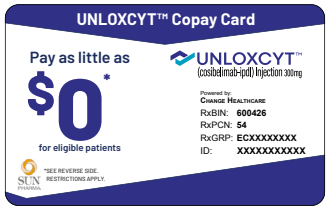
REFERENCES: 1. UNLOXCYT™ [prescribing information]. Waltham, MA: Checkpoint Therapeutics, Inc. November 2025. **2.** Ruiz ES, Muñoz-Couselo E, Montaudié H, et al. Efficacy and safety of cosibelimab in advanced cutaneous squamous cell carcinoma: results from a Pivotal Open-label Study with a median follow-up of ≥2 years. *J Am Acad Dermatol.* 2026;94(1):48-56. doi:10.1016/j.jaad.2025.09.009 **3.** Idris OA, Westgate D, Saadaie Jahromi B, Shebrain A, Zhang T, Ashour HM. PD-L1 inhibitor cosibelimab for cutaneous squamous cell carcinoma: comprehensive evaluation of efficacy, mechanism, and clinical trial insights. *Biomedicines.* 2025;13(4):889. doi:10.3390/biomedicines13040889 **4.** Chen RY, Zhu Y, Shen YY, et al. The role of PD-1 signaling in health and immune-related diseases. *Front Immunol.* 2023;14:1163633. doi:10.3389/fimmu.2023.1163633 **5.** KEYTRUDA® [prescribing information]. Rahway, NJ: Merck & Co., Inc. February 2026. **6.** LIBTAYO® [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. October 2025. **7.** Gorelik L, Avgerinos G, Kunes Y, Marasco WA. Preclinical characterization of a novel fully human IgG1 anti-PD-L1 mAb CK-301. Abstract #4606. Presented at: American Association for Cancer Research (AACR) Annual Meeting; April 1-5, 2017; Washington, DC. **8.** The Skin Cancer Foundation. Have you heard of cutaneous squamous cell carcinoma? Accessed August 23, 2025. https://www.skincancer.org/blog/have-you-heard-of-cutaneous-squamous-cell-carcinoma **9.** Mansouri B, Housewright CD. The treatment of actinic keratoses—the rule rather than the exception. *J Am Acad Dermatol.* 2017;153(11):1200. doi:10.1001/jamadermatol.2017.3395. **10.** Nanz L, Keim U, Katalinic A, Meyer T, Garbe C, Leiter U. Epidemiology of keratinocyte skin cancer with a focus on cutaneous squamous cell carcinoma. *Cancers (Basel).* 2024;16(3):606. doi:10.3390/cancers16030606 **11.** Rogers EM, Connolly KL, Nehal KS, Dusza SW, Rossi AM, Lee E. Comorbidity scores associated with limited life expectancy in the very elderly with nonmelanoma skin cancer. *J Am Acad Dermatol.* 2018;78(6):1119-1124. doi:10.1016/j.jaad.2017.12.048 **12.** Song X, Chen CI, Konidaris G, Zimmerman NM, Ruiz E. Real-world analysis of cost, treatment patterns, and outcomes of patients with metastatic cutaneous squamous cell carcinoma in the US. *Expert Rev Pharmacoecon Outcomes Res.* 2023;23(8):911-920. doi:10.1080/14737167.2023.2223982 **13.** Jiang R, Fritz M, Que SKT. Cutaneous squamous cell carcinoma: an updated review. *Cancers.* 2024;16(10):1800. doi:10.3390/cancers16101800 **14.** Kennedy-Martin T, Curtis S, Faries D, et al. A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results. *Trials.* 2015;16:495. doi:10.1186/s13063-015-1023-4 **15.** Pitkala KH, Strandberg TE. Clinical trials in older people. *Age Ageing.* 2022;51:1-9. doi:10.1093/ageing/afab282 **16.** Yin Q, Wu L, Han L, et al. Immune-related adverse events of immune checkpoint inhibitors: a review. *Front Immunol.* 2023;14:1167975. doi:10.3389/fimmu.2023.1167975 **17.** Kuzmanovszki D, Kiss N, Tóth B, et al. Real-world experience with cemiplimab treatment for advanced cutaneous squamous cell carcinoma-a retrospective single-center study. *J Clin Med.* 2023;12(18):5966. doi:10.3390/jcm12185966 **18.** Koch Hein EC, Vilbert M, Hirsch I, et al. Immune checkpoint inhibitors in advanced cutaneous squamous cell carcinoma: real-world experience from a Canadian comprehensive cancer centre. *Cancers (Basel).* 2023;15(17):4312. doi:10.3390/cancers15174312 **19.** Data on file. CK-301-101 Clinical Study Report Table 14.1.4.1. Sun Pharmaceuticals, Inc. Princeton, NJ. **20.** Data on file. CK-301-101 Clinical Study Report Overview. Sun Pharmaceuticals, Inc. Princeton, NJ. **21.** Delgado A, Guddati AK. Clinical endpoints in oncology – a primer. *Am J Cancer Res.* 2021;11(4):1121-1131. **22.** Clingan P, Ladwa R, Brungs D, et al. Efficacy and safety of cosibelimab, an anti-PD-L1 antibody, in metastatic squamous cell carcinoma. *J Immunother Cancer.* 2023;11:e007637. doi:10.1136/jitc-2023-007637 **23.** Ruiz ES, Muñoz-Couselo E, Montaudié H, et al. Efficacy and safety of cosibelimab in advanced cutaneous squamous cell carcinoma: results from a Pivotal Open-label Study with a median follow up of ≥2 years. Supplementary Appendix. *J Am Acad Dermatol.* 2026;94(1):48-56. https://www.jaad.org/article/S0190-9622(25)02791-4/fulltext **24.** Data on file. CK-301-101 Clinical Study Report Tables 16.2.4.1-16.2.4.9. Sun Pharmaceuticals, Inc. Princeton, NJ. **25.** Data on file. CK-301-101 Best Clinical Response Chart. Sun Pharmaceuticals, Inc. Princeton, NJ.

Comprehensive support



UNLOXCYT SUPPORT™ is dedicated to supporting healthcare professionals with comprehensive resources for starting patients on UNLOXCYT™. After your patients have been prescribed UNLOXCYT, enroll them in UNLOXCYT SUPPORT. Learn how we can support you and your patient every step of the way.

Enrolling Patients in UNLOXCYT SUPPORT

There are 2 ways to enroll patients:

Visit UnloxcytSupport.com and complete the digital enrollment form

- A seamless e-enrollment experience that does not require a log-in or password

Fax the patient enrollment form to 1-855-786-7458

- Patient consent can be obtained electronically from a mobile device or via email

Benefit Verification

Streamlined results from the benefit investigation are delivered quickly with the benefit verification. UNLOXCYT SUPPORT has a team of skilled Benefit Verification Specialists (BVS) with payer and practice operations experience.

Results of the benefit verification are faxed to your office the same or next day.*

Coordination & Financial Support

UNLOXCYT SUPPORT is here to help eligible patients get their medication by offering support with out-of-pocket costs. **For more information, visit UnloxcytPro.com/support**

UNLOXCYT Copay Program†

- Patients with commercial insurance may pay as little as $0‡
  - Enrollment in UNLOXCYT SUPPORT is not required to obtain the UNLOXCYT Copay Card

Patient Assistance Program

- Patients who are underinsured or uninsured may be eligible to receive free medication§

UNLOXCYT is available through our limited distribution network

Authorized Specialty Distributors

AmerisourceBergen Specialty Distribution
Phone: 1-800-746-6273 | asdhealthcare.com

CuraScript SD
Phone: 1-877-599-7748 | curascriptsd.com/contact-us

McKesson Specialty Health
Phone: 1-800-482-6700 | oncology.mckessonspecialtyhealth.com

Cardinal Health Specialty Distribution
Phone: 1-877-453-3972 | specialtyonline.cardinalhealth.com

McKesson Plasma and Biologics
Phone: 1-877-625-2566 | connect.mckesson.com

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SUN PHARMA does not recommend the use of any particular distributor or specialty pharmacy.

*Most completed enrollment forms received before 1:00 PM ET receive verification of benefits (VOB) the same day or the next day; most completed forms received after 1:00 PM ET receive VOB the next day.
†See full Terms and Conditions at unloxcytpro.com/support for UNLOXCYT Copay Program.
‡Offer not valid for patients enrolled in government health plans (Medicare, Medicaid, VA/DOD, etc). See full Terms and Conditions.
§See full Terms and Conditions at unloxcytpro.com/support for UNLOXCYT Patient Assistance Program.

UNLOXCYT™, an evolution in checkpoint inhibition—providing a balance of durable efficacy and a proven tolerability profile[1-4]

Durable Efficacy[1,2]

Durable responses in both mCSCC and laCSCC; median DOR not yet reached in either group

Proven Tolerability Profile[1]

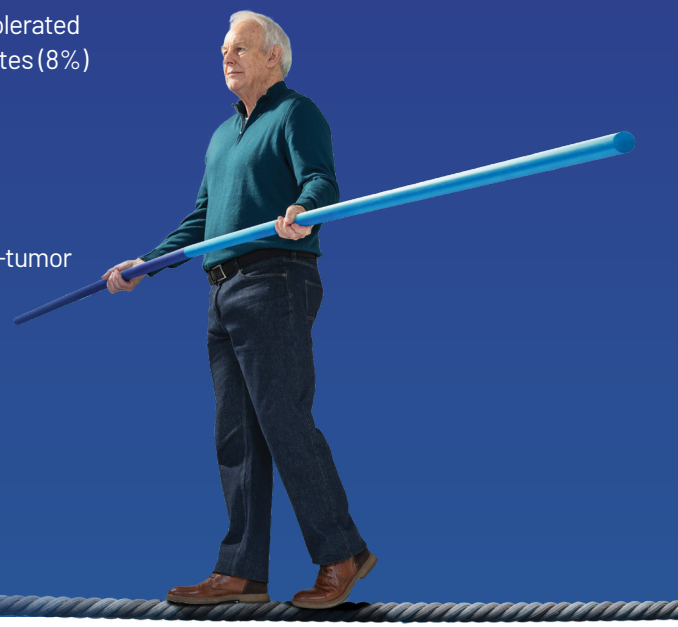
Low incidence of Grade ≥3 imARs; well tolerated with low permanent discontinuation rates (8%)

Multifaceted MOA[1-3,*]

Helps restore the adaptive immune response and engage the innate immune system

Preserves PD-L2 Signaling[1-4]

Helps maintain immune tolerance in non-tumor tissues by preserving PD-L2 signaling, reducing off-target effects and imARs



Not an actual patient.

The first and only checkpoint inhibitor in aCSCC that helps restore the adaptive immune response and engage the innate immune system while preserving PD-L2 signaling[1-6]

aCSCC=advanced cutaneous squamous cell carcinoma (metastatic and locally advanced disease); DOR=duration of response; imAR=immune-mediated adverse reaction; laCSCC=locally advanced cutaneous squamous cell carcinoma; mCSCC=metastatic cutaneous squamous cell carcinoma; MOA=mechanism of action; PD-L2=programmed death-ligand 2.

*The MOA of UNLOXCYT is based on in vitro data. Preclinical in vitro data may not translate to clinical outcomes.[1,7]

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