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FDA approves label update for UNLOXCYT™ (cosibelimab-ipdl) based on longer-term data that demonstrated improved clinical outcomes in advanced cutaneous squamous cell carcinoma (aCSCC)

- As the first and only PD-L1 immune checkpoint inhibitor approved for aCSCC, UNLOXCYT is an evolution in checkpoint inhibition, offering a balance of durable clinical responses and acceptable tolerability—a key consideration for a patient population that is often living with other comorbidities.
- The pivotal open-label UNLOXCYT trial included patients with metastatic CSCC (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation. The long-term follow-up analysis demonstrated an improvement in the primary endpoint, objective response rate (ORR), including more complete responses compared with the primary analysis for both groups, with ≥50% of patients experiencing an objective response.
- The median duration of response (DOR) (secondary endpoint) improved with longer follow-up and was not reached in either the mCSCC or laCSCC cohorts at the time of analysis, highlighting the durability of responses observed with UNLOXCYT.
- There were no changes to the safety profile of UNLOXCYT, including immune-mediated adverse reactions (imARs), with this label update.
- The long-term results from the pivotal open-label study of UNLOXCYT in aCSCC were published in the *Journal of the American Academy of Dermatology (JAAD)*, further validating the strength of the data.

MUMBAI, INDIA and PRINCETON, NJ., November 25, 2025 (ET) / November 26, 2025 (IST) – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, "Sun Pharma")) today announced the U.S. Food and Drug Administration (FDA) approved an updated label for UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The updated label now incorporates long-term follow-up data from the pivotal CK-301-101 trial, a multicenter, multicohort, open-label study of 109 patients (31 with laCSCC; 78 with mCSCC), which showed patients receiving UNLOXCYT experienced durable clinical responses.

At least 50% of patients in the trial achieved the primary endpoint of objective response. In addition, 14% of mCSCC patients and 32% of laCSCC patients achieved stable disease. At the time of the follow-up analysis, the median duration of response had not been reached in either group. Many clinical trial participants achieved a rapid response; median time to response was 1.9 months (range: 1.6-16.9) and 3.6 months (range: 1.7-10.1) in mCSCC and laCSCC, respectively.

In the CK-301-101 pivotal trial, the most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection. 53 patients (24%) in this study experienced imARs (any grade), with a low incidence of high-grade events. Two patients (0.9%) experienced high-grade imARs; both were Grade 3 dermatologic imARs. There were no treatment-related deaths.

UNLOXCYT restores the adaptive immune response, enabling T cells to recognize cancer cells by inhibiting the binding of PD-L1 with PD-1 on T cells and B7.1 on antigen-presenting cells. UNLOXCYT also engages the innate immune system through an active fragment crystallizable (Fc) domain that binds to natural killer (NK) cells to induce antibody-dependent cell-mediated cytotoxicity (ADCC). UNLOXCYT also spares PD-L2, which may help preserve immune tolerance in non-tumor tissues, such as lung and liver, potentially limiting off-target effects and imARs.

“The longer-term results confirm that UNLOXCYT represents an advancement in the available treatment options for people living with aCSCC,” said Richard Ascroft, CEO, Sun Pharma North America. “As a company committed to addressing the unmet needs of the patient communities we support, these pivotal data highlight that more patients responded and maintained their responses to UNLOXCYT for longer than observed in the primary analysis. The updated label reinforces UNLOXCYT as an evolution in checkpoint inhibition.”

UNLOXCYT was initially approved by the FDA in 2024. This updated label approval further underscores Sun Pharma’s commitment to advancing data-driven innovation and expanding differentiated immunotherapy treatment options within its growing cutaneous oncology portfolio. With this updated label, Sun Pharma intends to commercially launch UNLOXCYT in early 2026.

“While there have been advances in aCSCC treatment, there still remains a significant unmet need for therapies that provide durable, long-term efficacy with acceptable tolerability. This is especially important in this aging population who are dealing with significant comorbidities,” said Emily Ruiz, MD, MPH, Associate Professor of Dermatology, Harvard Medical School, Academic Director of the Micrographic Surgery Center at Brigham and Women’s Hospital, co-founder of Skin Cancer Champions, and primary author on the long-term analysis publication. “For many aCSCC patients who are over the age of 65 and dealing with comorbidities, UNLOXCYT provides an important, new treatment option that balances both efficacy and tolerability.”

Key Clinical Data From Updated Analysis (CK-301-101 Study):

Efficacy Endpoints	**mCSCC n=78**	**laCSCC n=31**
Objective Response Rate (ORR)		
ORR, n (%) (95% CI)	39 (50) (38, 62)	17 (55) (36, 73)
Complete response, n (%)	10 (13)	8 (26)
Partial response, n (%)	29 (37)	9 (29)
Duration of Response (DOR)[a]		
Number of responders	n=39	n=17
Median DOR in months[b] (range)	NR (1.4+, 45.3+)	NR (8.3, 31.3+)
Responders with observed DOR ≥ 6 months, n (%)[c]	33 (85)	17 (100)
Responders with observed DOR ≥ 12 months, n (%)[c]	26 (67)	15 (88)

CI: confidence interval; NR: not reached; +: Denotes ongoing at last assessment.
[a] Median follow up time: mCSCC: 29.3 months; laCSCC: 24.1 months.
[b] Based on Kaplan-Meier estimate.
[c] The numerator includes the number of patients whose observed DOR reached at least the specified times of 6 or 12 months. Patients who did not have the opportunity to reach the specified timepoint were included in the denominator only.

Incidence of CSCC

CSCC is the second most common type of skin cancer in the United States, with approximately 1 million people diagnosed annually. While most cases are localized tumors amenable to curative resection, each year in the United States approximately 40,000 cases progress to an advanced stage and approximately 15,000 people die of this disease. These patients with advanced-stage disease face limited treatment options and remain a population with a high unmet need.

“This label update reinforces the importance of therapeutic diversity in advanced CSCC,” said Dr. David Miller, Co-Director, NMSC Multi-Disciplinary Clinic, Mass General Brigham Cancer Institute. “Having access to a treatment option that works in a different way than other checkpoint inhibitors can only benefit patients who are fighting this disease and demand an efficacious treatment with acceptable tolerability.”

Following the FDA’s approval of the UNLOXCYT label, Sun Pharma will continue to focus on ensuring all appropriate patients have access to UNLOXCYT while engaging with pathway and guideline groups, such as the National Comprehensive Cancer Network® (NCCN®),[1] to consider this important treatment option for future updates.

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims responsibility for their application or use in any way.

Reference: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Squamous Cell Skin Cancer V.1.2026. © National Comprehensive Cancer Center, Inc. 2025. All rights reserved. Accessed November 6, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.

About Cutaneous Squamous Cell Carcinoma

Important risk factors for CSCC include chronic ultraviolet exposure and immunosuppressive conditions. In addition to being life-threatening, CSCC causes significant functional morbidities and cosmetic deformities due to tumors that commonly arise in the head and neck region and that invade blood vessels, nerves, and vital organs such as the eye or ear.

About UNLOXCYT™ (cosibelimab-ipdl)

UNLOXCYT 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. UNLOXCYT was recently named a finalist for the 2025 Prix Galien USA Bridges Award, recognizing it as one of the year’s most significant biomedical advancements.

Please see the INDICATIONS and IMPORTANT SAFETY INFORMATION below.

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.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)
Sun Pharma is the world's leading specialty generics company with a presence in innovative medicines, generics and consumer healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as global Emerging Markets. Sun

Pharma's high-growth global Innovative Medicines portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for about 20% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multicultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on LinkedIn & X (Formerly Twitter).

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