



FOR IMMEDIATE RELEASE

Sun Pharma Announces UNLOXCYT® (cosibelimab-ipdl) Has Received a Category 2A Preferred Designation in the Updated NCCN Guidelines for Locally Advanced Cutaneous Squamous Cell Carcinoma (laCSCC) Patients Who Are Not Candidates for Curative Surgery or Curative Radiation

MUMBAI, INDIA and PRINCETON, NJ (October 20, 2026) – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, (together with its subsidiaries and/or affiliated companies, “Sun Pharma”) today announced that UNLOXCYT® (cosibelimab-ipdl) has been elevated to a National Comprehensive Cancer Network® (NCCN®) Category 2A recommended option for patients with locally advanced cutaneous squamous cell carcinoma (laCSCC) who are not candidates for curative surgery or curative radiation.

This is an addition to the Category 2A designation in metastatic cutaneous squamous cell carcinoma (mCSCC), which was assigned to UNLOXCYT in 2025.

UNLOXCYT was approved by the U.S. Food and Drug Administration (FDA) in 2024 and is indicated for the treatment of adults with mCSCC or laCSCC who are not candidates for curative surgery or curative radiation. The recommended dosage of UNLOXCYT is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks. UNLOXCYT is the first and only FDA-approved PD-L1-blocking antibody for advanced CSCC (aCSCC).

The evidence submitted to NCCN in support of the change was based on the pivotal registration study, in which 55% of patients achieved an objective response, including 26% who achieved a complete response. Responses were durable: at a median follow-up of 24.1 months; median duration of response had not been reached (range: 8.3 to 31.3+ months). In addition, fewer than 1% of patients experienced a high-grade (Grade 3-5) immune-mediated adverse reaction (imARs)—an important consideration in this patient population. There were no grade 4 or 5 imARs.

“The NCCN Guidelines play an important role in helping physicians evaluate appropriate treatment options for patients across different disease settings,” said **Ahmad Naim, MD, Senior Vice President, North American Chief Medical Officer, Sun Pharma**. “The elevation of UNLOXCYT to a Category 2A recommendation for patients with laCSCC marks an important milestone, validating the growing body of clinical evidence supporting UNLOXCYT and reflecting increasing confidence among oncology experts in its role as a treatment option for patients with this challenging disease.”

NCCN is an alliance of 34 leading cancer centers in the U.S. Its Clinical Practice Guidelines in Oncology, referred to as the NCCN Guidelines, provide recommendations for the prevention, diagnosis, evaluation, and treatment of different types of cancer. The NCCN Guidelines are among the most influential clinical guidelines in cancer care, offering evidence-based, expert-



developed recommendations intended to help clinicians make treatment decisions for patients with cancer.

One such expert clinician is **Dr. Francis Worden, Clinical Professor of Internal Medicine at the University of Michigan Rogel Cancer Center**, whose institution is one of the 34 NCCN member cancer centers in the alliance.

Dr. Worden said, “This guideline update reflects the strength of the published evidence supporting the use of UNLOXCYT as first line treatment for laCSCC. In the pivotal study, patients experienced durable and clinically meaningful responses. UNLOXCYT also demonstrated a low incidence of high-grade imARs—an important consideration when selecting immune checkpoint inhibitor therapy for a patient population that is mainly elderly and is often afflicted with other health issues. These clinical outcomes may be explained by the mechanism of action that restores adaptive immunity, engages innate immunity through antibody-dependent cellular cytotoxicity (ADCC), and preserves PD-L2 signaling that may be linked to the presence of some immune tolerance in non-tumor tissues.”

NCCN Guidelines also have a meaningful impact on patient access because they inform payer coverage policies, prior-authorization criteria, institutional formularies, and clinical pathways.

“For patients with laCSCC—many of whom are older, medically complex, and vulnerable to treatment-related complications—access to a therapy that offers durable responses together with a low rate of high-grade imARs is especially important. NCCN recognition helps ensure that appropriate patients can receive this treatment up front without unnecessary access barriers,” said **Mark Gimbert, Senior Vice President, Head of Market and Patient Access, North America, Sun Pharma**.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma (CSCC) is among the most common skin cancers worldwide. While early stages are treatable, an estimated 40,000 US patients each year progress to advanced disease, resulting in nearly 15,000 deaths.

Important risk factors for CSCC include chronic ultraviolet radiation 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 Sun Pharma in Cutaneous Oncology

For more than two decades, Sun Pharma has built on its established leadership in dermatology to advance care for people impacted by skin cancer. Working in collaboration with the broader skin cancer community, the company is focused on addressing needs across the disease continuum—from precancerous conditions to advanced skin cancers. With a dedicated cutaneous oncology team and a growing focus in specialty medicines, Sun Pharma applies scientific rigor, real-world insight, and partnership to support meaningful progress in care and improve continuity for patients, caregivers, and clinicians.



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.

IMPORTANT SAFETY INFORMATION

WARNING AND PRECAUTIONS

Severe and Fatal Immune-mediated Adverse Reactions: Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, including, but not limited to, immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and renal dysfunction, and dermatologic adverse reactions.

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. 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.

Withhold or permanently discontinue UNLOXCYT based on the severity of reaction. If UNLOXCYT requires interruption or discontinuation, administer systemic corticosteroids (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 reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

UNLOXCYT 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 Colitis

UNLOXCYT can cause immune-mediated colitis, which may present with diarrhea, abdominal pain, and lower gastrointestinal (GI) bleeding. Cytomegalovirus infection/reactivation has occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.



Immune-Mediated Hepatitis

UNLOXCYT can cause immune-mediated hepatitis, defined as requiring the use of systemic corticosteroids and the absence of a clear alternate etiology.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

UNLOXCYT can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity

Hypophysitis

UNLOXCYT can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity

Thyroid Disorders

UNLOXCYT 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 UNLOXCYT depending on severity

Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis

UNLOXCYT can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity

Immune-Mediated Nephritis with Renal Dysfunction

UNLOXCYT can cause immune-mediated nephritis, defined as the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology.

Immune-Mediated Dermatologic Adverse Reactions

UNLOXCYT can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue UNLOXCYT depending on severity

Other Immune-Mediated Adverse Reactions

Cardiac/Vascular: Myocarditis, pericarditis, vasculitis.

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



Ocular: Uveitis, iritis, ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur.

Gastrointestinal: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis.

Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.

Endocrine: Hypoparathyroidism.

Hematologic/Immune: Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Myocarditis-Myositis-Myasthenia Gravis (or Myasthenia-like) Overlap Syndrome, reporting as the co-occurrence of either two or all three adverse reactions.

Infusion-Related Reactions: UNLOXCYT can cause severe or life-threatening infusion-related reactions. 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 system 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. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause).

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 ($\geq 10\%$) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

USE IN SPECIFIC POPULATIONS

Lactation: Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 4 months after the last dose of UNLOXCYT.



To report side effects of UNLOXCYT to FDA: visit www.fda.gov/medwatch or call 1-800FDA-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 [Full Prescribing Information](#) for additional Important Safety Information.

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's high growth 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 multi-cultural 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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