

Sun Pharmaceutical Industries Limited
Sun House, Plot No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai – 400 063, Maharashtra, INDIA.
Tel.: (91-22) 4324 4324
Fax: (91-22) 4324 4343
Website: www.sunpharma.com
Email: secretarial@sunpharma.com
CIN: L24230GJ1993PLC019050



FOR IMMEDIATE RELEASE

At the ASCO® 2026 Annual Meeting, Sun Pharma to Present Pivotal Long-Term Follow-up Data on UNLOXCYT™ (cosibelimab-ipdl)

Nearly 27% of patients experienced a complete response; median duration of response not reached; only 1 patient experienced a Grade ≥ 3 immune-related adverse event

Second Largest Prospective Study of Locally Advanced Cutaneous Squamous Cell Carcinoma (laCSCC) Patients

May 26, 2026, MUMBAI, INDIA and PRINCETON, NJ – 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 the company will share updated results from the locally advanced cutaneous squamous cell carcinoma (laCSCC) expansion cohort from the pivotal [CK-301-101](#) trial of UNLOXCYT™ (cosibelimab-ipdl) at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting on May 31, 2026 in Chicago.

In the investigator-reviewed data being presented at ASCO, 64 patients with laCSCC received ≥ 1 dose of UNLOXCYT. The median age of patients in the cohort was 77 years old and 66% were male. This reflects the population commonly seen in clinical practice. Patients received a median of 29 doses over a median treatment duration of 60 weeks. The objective response rate was 50%, including 17 (27%) complete responses and 15 (23%) partial responses. Over a median follow-up of 31 months, responses were durable and the median duration of response was not yet reached.

"These data support clinically meaningful efficacy within this patient population. We observed a high rate of complete responses in patients with laCSCC, which is associated with long-term clinical outcomes. The durability of these responses, a primary therapeutic objective, was achieved alongside a manageable safety profile," said **Rahul Ladwa, MBChB, BSc, FRACP, MPhil, Medical Oncologist at the Princess Alexandra Hospital and Greenslopes Private Hospital; Associate Professor, The University of Queensland, Australia; and presenting study co-author at ASCO.**

The safety profile was comparable to what was observed in an earlier analysis of a smaller cohort.

- The most common adverse events (AEs) were anemia and diarrhea, recorded in 17 (27%) patients each.
- Immune-related adverse reactions (irAEs) were observed in 22 (34%) patients.
- Grade ≥ 3 irAEs occurred in 1 (2%) patient and were dermatologic in nature (maculo-papular and pruritic rashes) and considered treatment-related.
- Treatment-emergent AEs (TEAEs) were reported in 61 (95%) patients and considered treatment-related in 50 (78%) patients; none were fatal.
- Grade ≥ 3 TEAEs were reported in 26 (41%) patients and considered treatment-related in 7 (11%).

"The findings from this large cohort of patients are impressive from both an efficacy and tolerability perspective. Patients with laCSCC are older and have many comorbidities, so we need treatment options that are both efficacious and well tolerated, so patients remain on therapy and experience meaningful benefit," said **Emily Ruiz, MD, MPH, Associate Professor of Dermatology, Harvard Medical School, Academic Director of the Micrographic Surgery Center at Brigham and Women's**

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Hospital; co-founder of Skin Cancer Champions; and study co-author. “Cosibelimab seems to work differently than other checkpoint inhibitors by restoring the adaptive immune response and engaging the innate immune system while preserving the PD-1/PD-L2 pathway. We believe this may explain the results we observe in these patients.”

Poster Presentation Details

- **Title:** Efficacy and safety of cosibelimab 800 mg every 2 weeks for locally advanced cutaneous squamous cell carcinoma: Updated follow-up from a pivotal study
- **Poster Session:** Melanoma/Skin Cancers
- **Abstract Number:** 9585
- **Poster Board Number:** 301
- **Date and Time:** May 31, 2026; 9:00am-12:00pm CDT
- **Presenter:** Dr. Rahul Ladwa

“We’re looking forward to presenting these data at ASCO’s Annual Meeting later this month, highlighting pivotal results from the second largest ever reported prospective study of laCSCC patients treated with PD-(L)1 monotherapy, reinforcing our commitment to the skin cancer community,” said **Ahmad Naim, MD, Senior Vice President, North America Chief Medical Officer, Sun Pharma.** “With a median duration of response not yet reached after more than two and a half years of follow-up, UNLOXCYT continues to demonstrate the kind of clinically meaningful efficacy with durable clinical responses and well-tolerated treatment option that patients with laCSCC need.”

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

UNLOXCYT (cosibelimab-ipdl) was approved at 1,200 mg Q3W because PK/PD modeling showed it provides similar overall exposure and PD-L1 receptor coverage as the trial regimen of 800 mg Q2W. Since checkpoint inhibitors have flat exposure-response curves, they have been utilized with more convenient dosing schedules if equivalent efficacy and safety are maintained. The safety analyses included patients who received both 800 mg Q2W and 1,200 mg Q3W.

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

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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.

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

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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.

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).

Disclaimer

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Contacts: Sun Pharma

Investors

Dr. Abhishek Sharma
Tel: +91 22 4324, Ext 2929
Tel Direct: +91 22 4324 2929
Mobile: +91 98196 86016
Email: abhi.sharma@sunpharma.com

Media

Gaurav Chugh
Tel: +91 22 4324 4324, Ext 5373
Tel Direct: +91 22 4324 5373
Mobile: +91 98104 71414
Email: gaurav.chugh@sunpharma.com

U.S. Media:

Robert Perry
Mobile: +1 609 921 4269
E-mail: robert.perry@sunpharma.com

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