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Sun Pharma Announces the Availability of UNLOXCYT™ (cosibelimab-ipdl) for Advanced Cutaneous Squamous Cell Carcinoma (aCSCC)

- UNLOXCYT is an evolution in checkpoint inhibition and is now available for the treatment of adults in the U.S. with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- UNLOXCYT offers a balanced treatment approach; the recently updated label now includes long-term data confirming durable efficacy and a proven tolerability profile.
- UNLOXCYT has a multifaceted mechanism of action (MOA)*; the first and only checkpoint inhibitor in aCSCC that helps restore the adaptive immune response and engages the innate immune system while preserving PD-L2 signaling.
- UNLOXCYT SUPPORT™ is focused on providing essential support for HCPs and aCSCC patients.

*The MOA of UNLOXCYT is based on in vitro data. Preclinical in vitro data may not translate to clinical outcomes.

MUMBAI, INDIA and PRINCETON, NJ. (January 15, 2026) – 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 [UNLOXCYT™](#) (cosibelimab-ipdl) is now available in the U.S. for healthcare professionals to prescribe for adults with mCSCC or laCSCC who are not candidates for curative surgery or curative radiation.

“Patients with unresectable or metastatic CSCC now have a new and important treatment option to manage their disease. UNLOXCYT is a novel anti-PD-L1 antibody that is capable of antibody-dependent cellular cytotoxicity and associated with clinically meaningful efficacy, as shown by a disease control rate of 71%,” said Ann W. Silk, MD, MS, medical oncologist at Dana-Farber Cancer Institute and Assistant Professor of Medicine at Harvard Medical School. “Because these patients tend to be older and have multiple comorbidities, it’s extremely valuable to have a therapy that offers durable disease control and proven tolerability.”

“UNLOXCYT is an evolution in checkpoint inhibition, combining durable efficacy with a proven tolerability profile for a group of aCSCC patients who traditionally would struggle to strike that therapeutic balance,” said Richard Ascroft, CEO of Sun Pharma North America. “Sun Pharma is committed to ensuring access from day one with the UNLOXCYT SUPPORT™ patient access and affordability program.”

The U.S. Food and Drug Administration (FDA) recently approved an updated label for UNLOXCYT to reflect long-term follow-up data from the pivotal CK-301-101 clinical trial. This study showed improvements in objective response rates (including more patients who achieved a complete response [CR]) and duration of response. The safety data did not change from the original UNLOXCYT label.

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Many patients in the pivotal trial experienced durable responses with UNLOXCYT. At least 50% demonstrated an objective response (complete or partial response), including 13% of mCSCC patients and 26% of laCSCC patients who achieved complete response. 71% of patients achieved disease control with UNLOXCYT, including patients with stable disease. The median duration of response has not yet been reached in either treatment group.

Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, during or after discontinuation of treatment. Females should use effective contraception and avoid breastfeeding during treatment.

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

Of particular note, no patients developed Grade 3 or 4 pneumonitis. Just 0.9% (two patients) experienced pneumonitis (Grade 2).

UNLOXCYT is available through a limited distribution network of authorized specialty distributors and one contracted specialty pharmacy. Healthcare professionals can visit UNLOXCYTPro.com for additional information. Sun Pharmaceuticals does not recommend the use of any particular distributor or specialty pharmacy.

For comprehensive support, UNLOXCYT SUPPORT is dedicated to supporting healthcare professionals and patients by providing resources for their journey on UNLOXCYT.

About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma 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.

INDICATIONS AND USAGE

UNLOXCYT (cosibelimab-ipdI) 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.

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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 ($\geq 10\%$) 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 1-800-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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Please see [Full Prescribing Information](#) for additional Important Safety Information.

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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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