

# FOR IMMEDIATE RELEASE

# **Sun Pharma Completes its Acquisition of Checkpoint Therapeutics**

**MUMBAI, India and PRINCETON, NJ (May 30, 2025)** – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associate companies, "Sun Pharma")) today announced the successful completion of its acquisition of Checkpoint Therapeutics, Inc. ("Checkpoint"), an immunotherapy and targeted oncology company. As part of the acquisition, Sun Pharma acquires UNLOXCYT<sup>TM</sup>, the first and only FDA-approved anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma.

"This acquisition exemplifies Sun Pharma's commitment to supporting patients and growing its innovative therapies business," said Dilip Shanghvi, Chairman & Managing Director of Sun Pharma. "By adding UNLOXCYT<sup>TM</sup>, we will be able to leverage our leadership in the onco-derm space to help patients access an important treatment option while growing our product portfolio."

# **Financial Terms**

Sun Pharma has acquired all outstanding shares of Checkpoint at a price of \$4.10 per share in cash, without interest, plus one non-tradable contingent value right (CVR) per share representing the right to receive up to an additional \$0.70 in cash, without interest, if certain specified milestones are met, as set out in the terms and conditions of the contingent value rights agreement.

# About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's leading specialty generics company with a presence in specialty, 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 specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% 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).

# About Cutaneous Squamous Cell Carcinoma

Cutaneous squamous cell carcinoma ("cSCC") is the second-most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1.8 million cases according to the Skin Cancer Foundation. Important risk factors for cSCC include chronic ultraviolet exposure and immunosuppressive conditions. While most cases are localized tumors amenable to curative resection, each year approximately 40,000 cases become advanced and an estimated 15,000 people in the United States die from this disease. In addition to being a life-threatening disease, 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.



# UNLOXCYT<sup>TM</sup> INDICATION and IMPORANT SAFETY INFORMATION

# INDICATION

UNLOXCYT<sup>TM</sup> (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic cSCC or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

# **IMPORTANT SAFETY INFORMATION**

#### Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions listed herein may not include all possible 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, and occur at any time after starting a PD-1/PD-L1– blocking antibody, including UNLOXCYT<sup>TM</sup>. While immune-mediated adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1–blocking antibodies. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests 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<sup>TM</sup> depending on the severity of the adverse reaction (see Dosage and Administration in <u>Prescribing Information</u>). In general, if UNLOXCYT<sup>TM</sup> 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<sup>TM</sup> can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibody, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 1% (3/223, Grade 2) of patients receiving UNLOXCYT<sup>TM</sup>.

#### Immune-Mediated Colitis

• UNLOXCYT<sup>TM</sup> can cause immune-mediated colitis, which may present with diarrhea, abdominal pain, and lower gastrointestinal 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 colitis occurred in 0.4% (1/223, Grade

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# 1) of patients receiving UNLOXCYT<sup>TM</sup>.

#### Immune-Mediated Hepatitis

• UNLOXCYT<sup>TM</sup> can cause immune-mediated hepatitis.

#### Immune-Mediated Endocrinopathies

#### Adrenal Insufficiency

 UNLOXCYT<sup>TM</sup> 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<sup>TM</sup> depending on severity. Adrenal insufficiency occurred in 0.9% (2/223) of patients receiving UNLOXCYT<sup>TM</sup>, including Grade 2 in 0.4% (1/223) of patients.

# Hypophysitis

• UNLOXCYT<sup>TM</sup> 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<sup>TM</sup> depending on severity.

# Thyroid Disorders

UNLOXCYT<sup>TM</sup> 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<sup>TM</sup> depending on severity. Hypothyroidism occurred in 10% (22/223) of patients receiving UNLOXCYT<sup>TM</sup>, including Grade 2 in 5% (10/223) of patients. Hyperthyroidism occurred in 5% (12/223) of patients receiving UNLOXCYT<sup>TM</sup>, including Grade 2 in 0.4% (1/223) of patients.

# Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis

• UNLOXCYT<sup>TM</sup> 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<sup>TM</sup> depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

• UNLOXCYT<sup>TM</sup> can cause immune-mediated nephritis.

# Immune-Mediated Dermatologic Adverse Reactions

• UNLOXCYT<sup>TM</sup> can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis,

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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 antibody. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue UNLOXCYT<sup>TM</sup> depending on severity. Immune-mediated dermatologic adverse reactions occurred in 7% (15/223) of patients receiving UNLOXCYT<sup>TM</sup>, including Grade 3 in 0.9% (2/223) of patients and Grade 2 in 4% (9/223) of patients.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 223 patients who received UNLOXCYT<sup>TM</sup> or were reported with the use of other PD-1/PD-L1– blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
  - o 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, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
  - 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.
  - Other (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.

# **Infusion-Related Reactions**

- UNLOXCYT<sup>TM</sup> can cause severe or life-threatening infusion-related reactions. Infusion-related infusion reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT<sup>TM</sup>.
- Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of Registered Office: SPARC, Tandalja, Vadodara – 390 012, Gujarat, INDIA.



infusion or permanently discontinue UNLOXCYT<sup>TM</sup> 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/PD-L1–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). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. 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**

Based on its mechanism of action, UNLOXCYT<sup>TM</sup> can cause fetal harm when administered to a
pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway
can lead to increased risk of immune-mediated rejection of the developing fetus, resulting in fetal
death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive
potential to use effective contraception during treatment with UNLOXCYT<sup>TM</sup> and for 4 months
after the last dose.

# **Common 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.

Please see full Prescribing Information.

# **Sun Pharma Contacts:**

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