



## Sun Pharma to Acquire Checkpoint Therapeutics

*Will add UNLOXCYT™ (cosibelimab-ipdl), the first and only FDA-approved anti-PD-L1 treatment for metastatic or locally advanced cutaneous squamous cell carcinoma (cSCC) to Sun Pharma's global onco-derm franchise*

*Will leverage Sun Pharma's global presence to accelerate patient access to UNLOXCYT™ (cosibelimab-ipdl)*

*Upfront cash payment of \$4.10 per share of common stock, representing aggregate upfront consideration of up to \$355 million*

*Stockholders will also receive a contingent value right for up to \$0.70 per share on achievement of a milestone*

*Acquisition is subject to approval by Checkpoint's stockholders and other customary closing conditions*

**Mumbai, India (March 10, 2025) and Waltham, Mass. (March 9, 2025)** – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, "Sun Pharma")) and Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint") today announced that they have entered into an agreement by which Sun Pharma will acquire Checkpoint, an immunotherapy and targeted oncology company.

Checkpoint is a Nasdaq-listed commercial-stage company focused on developing novel treatments for patients with solid tumor cancers. Checkpoint has received approval from the U.S. Food & Drug Administration (FDA) for UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

Dilip Shanghvi, Chairman & Managing Director of Sun Pharma, said, "Combining UNLOXCYT, an FDA-approved anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma, with Sun Pharma's global presence means patients with cSCC may soon have access to an important, new treatment option. The acquisition further bolsters our innovative portfolio in onco-derm therapy."

"I am proud of the dedication and passion of our team at Checkpoint that allowed us to achieve the first and only FDA-approved anti-PD-L1 treatment for patients with advanced cSCC, and we are excited to enter this transaction with Sun Pharma as the next step to bringing UNLOXCYT to cSCC patients in need of a differentiated immunotherapy treatment option," said James Oliviero, President and Chief Executive Officer of Checkpoint. "Sun Pharma is aligned with Checkpoint's commitment to improving the lives of skin cancer patients, and I believe this transaction will maximize value for our stockholders and provide accelerated access to UNLOXCYT in the United States, Europe and other markets worldwide."



## Transaction Summary

Upon completion of the transaction, Sun Pharma will acquire all outstanding shares of Checkpoint and Checkpoint stockholders will receive, for each share of common stock they hold, an upfront cash payment of \$4.10, without interest, and a non-transferable contingent value right (CVR) entitling the stockholder to receive up to an additional \$0.70 in cash, without interest, if cosibelimab is approved prior to certain deadlines in the European Union pursuant to the centralized approval procedure or in Germany, France, Italy, Spain or the United Kingdom, subject to the terms and conditions in the contingent value rights agreement.

The upfront cash payment of \$4.10 per share of common stock represents a premium of approximately 66.0% to Checkpoint's closing share price on March 7, 2025, the last trading day prior to today's announcement.

In connection with the transaction, Checkpoint, Sun Pharma and Fortress Biotech, Inc., Checkpoint's controlling stockholder ("Fortress"; Nasdaq: FBIO), have entered into a royalty agreement, under which following the closing of the transaction Fortress would be entitled to receive royalty payments based on future sales of cosibelimab during a specified term, in lieu of royalty rights that were granted to Fortress in connection with its founding of Checkpoint.

In connection with the evaluation of Checkpoint's strategic alternatives, the Checkpoint board of directors (the "Board") formed a special committee of independent and disinterested directors (the "Special Committee"), which led the review and negotiations for this transaction. The Special Committee, with the assistance of its independent financial and legal advisors, conducted a comprehensive review of potential strategic alternatives available to Checkpoint and ultimately determined that the compelling and certain cash consideration and meaningful upside presented by the CVRs in this transaction provides superior risk-adjusted value relative to Checkpoint's standalone prospects and other available alternatives. The Special Committee unanimously approved, and recommended that Checkpoint's Board approve, the proposed transaction. After considering this recommendation, Checkpoint's Board unanimously approved the proposed transaction. In arriving at its unanimous recommendation in favor of the transaction, the Special Committee considered several additional factors which will be outlined in public filings to be made by Checkpoint.

The transaction is expected to be completed in the second calendar quarter of 2025. The transaction is subject to customary closing conditions, including required regulatory approvals and approval by the holders of a majority of the voting power of outstanding shares of Checkpoint common stock, and by the holders of a majority of the shares of Checkpoint common stock that are not held by Fortress or by certain other affiliates of Checkpoint.

For the nine-month period ending September 2024, Checkpoint reported \$0.04 million in revenue and a net loss of \$27.3 million. The R&D expense for the nine-month period was \$19.3 million. As of September 30, 2024, Checkpoint had a cash balance of \$4.7 million, outstanding accounts payable and accrued expenses of \$15.6 million, and outstanding accounts payable and accrued expenses –



related party of \$2.0 million.

In connection with the transaction, Fortress, which holds a majority of Checkpoint's outstanding voting power, has agreed to vote in favor of the transaction.

#### **Advisors**

Barack Ferrazzano Kirschbaum & Nagelberg LLP and Allen Overy Shearman Sterling US LLP are serving as legal advisors to Sun Pharma.

Locust Walk is serving as the exclusive financial advisor to Checkpoint and lead financial advisor to Checkpoint on the transaction.

Cooley LLP and Morris, Nichols, Arsht & Tunnell LLP are serving as legal advisors to the Special Committee. Kroll, LLC is serving as financial advisor to the Special Committee.

Alston & Bird LLP is serving as legal advisor to Checkpoint.

#### **About 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.

#### **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](http://www.sunpharma.com) and follow us on LinkedIn & X (Formerly Twitter).

#### **About Checkpoint Therapeutics, Inc.**

Checkpoint is a commercial-stage immunotherapy and targeted oncology company focused on the



acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint has received approval from the U.S. FDA 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. Additionally, Checkpoint is evaluating its lead investigational small-molecule, targeted anti-cancer agent, olafertinib (formerly CK-101), a third-generation epidermal growth factor receptor (EGFR) inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer. Checkpoint is headquartered in Waltham, MA and was founded by Fortress. For more information, visit [www.checkpointtx.com](http://www.checkpointtx.com).

### **Forward Looking Statements**

This press release contains express or implied forward-looking statements related to Sun Pharma, Checkpoint and the proposed acquisition.

All statements other than statements of historical fact are statements that could be deemed “forward-looking statements” within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995, including all statements regarding the intent, belief or current expectation of the companies and members of their senior management teams. Words such as “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target,” variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words.

Examples of such forward-looking statements include, but are not limited to, express or implied:

- statements regarding the transaction and related matters, including the benefits of and timeline for closing the transaction, any payments under the CVRs, prospective performance and opportunities, post-closing operations and the outlook for the companies’ businesses;
- statements of targets, plans, objectives or goals for future operations, including those related to Sun Pharma’s and Checkpoint’s products, product research, product development, product introductions and product approvals as well as cooperation in relation thereto;
- statements containing projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures;
- statements regarding future economic performance, future actions and outcome of contingencies such as legal proceedings; and
- statements regarding the assumptions underlying or relating to such statements.

These statements are based on current plans, estimates and projections and are not predictions of actual performance. By their very nature, forward-looking statements involve inherent risks and uncertainties. Sun Pharma and Checkpoint each caution that a number of important factors,



including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements.

Factors that may affect future results and may cause these forward-looking statements to be inaccurate include, but are not limited to: uncertainties as to the timing of completion of the merger; uncertainties as to whether Checkpoint's stockholders will vote to approve the transaction; the possibility that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction (or only grant approval subject to adverse conditions or limitations); the possibility that the proposed transaction may not be completed in the time frame expected by Sun Pharma and Checkpoint, or at all; failure to realize the anticipated benefits of the proposed transaction in the time frame expected, or at all; the effects of the transaction on relationships with employees, other business partners or governmental entities; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed transaction; significant or unexpected costs, charges or expenses resulting from the proposed transaction; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Sun Pharma's shares or Checkpoint's common stock and/or Sun Pharma's or Checkpoint's operating results; the difficulty of predicting the timing or outcome of regulatory approvals or actions; the risks related to non-achievement of the CVR milestone and that holders of the CVRs will not receive payments in respect of the CVRs; other business effects, including the effects of industry, economic or political conditions outside of the companies' control; transaction costs; actual or contingent liabilities; risk of litigation and/or regulatory actions related to the proposed acquisition; adverse impacts on business, operating results or financial condition in the future due to pandemics, epidemics or outbreaks, and their impact on Sun Pharma's and Checkpoint's respective businesses, operations, supply chain, patient enrollment and retention, clinical trials, strategy, goals and anticipated milestones; government-mandated or market-driven price decreases for Sun Pharma's or Checkpoint's products; the existence or introduction of competing products; reliance on information technology; Sun Pharma's or Checkpoint's ability to successfully market current and new products; Sun Pharma's, Checkpoint's and their collaborators' ability to continue to conduct research and clinical programs; and exposure to product liability and legal proceedings and investigations. Further risks and uncertainties that could cause actual results to differ materially from the results anticipated by the forward-looking statements are detailed from time to time in Checkpoint's periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and the definitive proxy statement to be filed by Checkpoint with the SEC in connection with the proposed transaction. These filings, when available, are available on the investor relations section of Checkpoint's website at <https://ir.checkpointtx.com> or on the SEC's website at <https://www.sec.gov>.

Any forward-looking statements speak only as of the date of this communication and are made based on the current beliefs and judgments of Sun Pharma's and Checkpoint's management, and the reader is cautioned not to rely on any forward-looking statements made by Sun Pharma or Checkpoint. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Unless required by law, each of Sun Pharma and Checkpoint is under



no duty and undertakes no obligation to update or revise any forward-looking statement after the distribution of this communication, whether as a result of new information, future events or otherwise.

### **Additional Information and Where to Find It**

This press release may be deemed to be solicitation material in respect of the proposed acquisition of Checkpoint by Sun Pharma pursuant to the Agreement and Plan of Merger, dated as of March 9, 2025, by and among Sun Pharma, Checkpoint and Snoopy Merger Sub, Inc., Checkpoint intends to file a preliminary and definitive proxy statement with the SEC in connection with a special meeting of stockholders to be held in connection with the proposed acquisition. The definitive proxy statement and a proxy card will be delivered to each Checkpoint stockholder entitled to vote at the special meeting in advance of thereof. This press release is not a substitute for the proxy statement, which will contain important information about the proposed transaction and related matters, or any other document that may be filed by Checkpoint with the SEC. BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, CHECKPOINT'S STOCKHOLDERS AND INVESTORS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY CHECKPOINT WITH THE SEC IN CONNECTION WITH THE PROPOSED ACQUISITION OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION AND THE PARTIES TO THE PROPOSED ACQUISITION. Investors and security holders will be able to obtain a free copy of the proxy statement and such other documents containing important information about Checkpoint, once such documents are filed with the SEC, through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Checkpoint makes available free of charge at its website at <https://ir.checkpointtx.com/> copies of materials it files with, or furnishes to, the SEC.

### **Participants in the Solicitation**

Checkpoint and its directors, and certain of its executive officers, consisting of Michael S. Weiss, Christian Béchon, Neil Herskowitz, Lindsay A. Rosenwald, Barry Salzman, Amit Sharma, who are the non-employee members of the Board of Directors of Checkpoint (the "Board"), and James Oliviero, President and Chief Executive Officer and a member of the Board, and Garrett Gray, Chief Financial Officer, may be deemed to be participants in the solicitation of proxies from Checkpoint's stockholders in connection with the proposed acquisition. Information regarding Checkpoint's directors and certain of its executive officers, including a description of their direct or indirect interests, by security holdings or otherwise, can be found under the captions "*Security Ownership of Certain Beneficial Owners and Management*," "*Executive Compensation*," and "*Director Compensation*" contained in Checkpoint's definitive proxy statement on Schedule 14A for Checkpoint's 2024 annual meeting of stockholders, which was filed with the SEC on April 2, 2024 and under Item 5.02 in the current reports on Form 8-K filed with the SEC on May 14, 2024 and January 10, 2025. To the extent holdings of Checkpoint's securities by its directors or executive officers have changed since the applicable "as of" date described in its 2024 proxy statement, such changes have been or will be reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Beneficial Ownership on Form 4 filed with the SEC, including (i) the Form 4s filed by Mr.



Béchon on May 16, 2024 and December 17, 2024; (ii) the Form 4s filed by Mr. Gray on May 24, 2024, June 28, 2024, December 17, 2024, December 20, 2024, January 31, 2025 and February 7, 2025; (iii) the Form 4s filed by Mr. Herskowitz on May 16, 2024 and December 17, 2024; (iv) the Form 4s filed by Mr. Oliviero on May 24, 2024, June 28, 2024, December 17, 2024, December 20, 2024, January 31, 2025 and February 11, 2025; (v) the Form 4s filed by Dr. Rosenwald on May 16, 2024 and December 17, 2024; (vi) the Form 4s filed by Mr. Salzman on May 16, 2024 and December 17, 2024; (vii) the Form 4 filed by Dr. Sharma on May 16, 2024; and (viii) the Form 4s filed by Mr. Weiss on May 16, 2024 and December 17, 2024. Additional information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, will be included in the definitive proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at [www.sec.gov](http://www.sec.gov) and Checkpoint's website at <https://ir.checkpointtx.com/>.

## **INDICATION and IMPORANT SAFETY INFORMATION**

### **INDICATION**

UNLOXCYT (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("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. 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 depending on the severity of the adverse reaction (see Dosage and Administration in Prescribing Information). In general, 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 pneumonitis occurred in 1% (3/223, Grade 2) of patients receiving UNLOXCYT.

#### Immune-Mediated Colitis

- UNLOXCYT 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 1) of patients receiving UNLOXCYT.

#### Immune-Mediated Hepatitis

- UNLOXCYT can cause immune-mediated hepatitis.

#### 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. Adrenal insufficiency occurred in 0.9% (2/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients.

##### *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. Hypothyroidism occurred in 10% (22/223) of patients receiving UNLOXCYT, including Grade 2 in 5% (10/223) of patients. Hyperthyroidism occurred in 5% (12/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients.

#### *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.

#### 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. Immune-mediated dermatologic adverse reactions occurred in 7% (15/223) of patients receiving UNLOXCYT, 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 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.
  - 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 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.
- 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/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 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 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](#).

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