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Checkpoint Therapeutics Reports First Quarter Financial Results and Recent Corporate Updates

UNLOXCYT™ (cosibelimab-ipdl) approved by U.S. FDA in December 2024 as first and only anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma

Special meeting of stockholders to vote on Merger to take place on May 28, 2025

WALTHAM, Mass., May 13, 2025 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a commercial-stage immunotherapy and targeted oncology company, today announced financial results for the first quarter ended March 31, 2025, and recent corporate updates.

Recent Corporate Updates:

- In December 2024, Checkpoint announced that the U.S. Food and Drug Administration ("FDA") approved 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. UNLOXCYT is the first and only programmed death ligand-1 ("PD-L1") blocking antibody to receive FDA marketing approval for this indication.
- In March 2025, Checkpoint announced that it entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sun Pharmaceutical Industries, Inc. ("Sun Pharma"), and a wholly owned subsidiary of Sun Pharma, with Checkpoint continuing as the surviving corporation of the transaction and a wholly owned subsidiary of Sun Pharma (the "Merger"). The total transaction value of the Merger, including the upfront cash payment and the maximum value of the contingent value right ("CVR"), is up to approximately \$416 million, and the Merger is expected to be completed in the second quarter of 2025. The transaction is subject to customary closing conditions, including required regulatory approvals and approval by the requisite majorities of Checkpoint's stockholders. In April 2025, the Merger Agreement was amended.
- Also in April 2025, Checkpoint filed the definitive proxy statement relating to the Merger. The special meeting of Checkpoint stockholders to vote on the Merger will be held on May 28, 2025.

Financial Results:

- **Cash Position:** As of March 31, 2025, Checkpoint's cash and cash equivalents totaled \$33.0 million, compared to \$6.6 million at December 31, 2024, an increase of \$26.4 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2025 were \$3.8 million, compared to \$8.5 million for the first quarter of 2024, a decrease of \$4.7 million. Research and development expenses for the first quarter of 2025 included \$0.7 million of non-cash stock expenses, compared to \$0.5 million for the first quarter of 2024.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2025 were \$7.4 million, compared to \$2.5 million for the first quarter of 2024, an increase of \$4.9 million. General and administrative expenses for the first quarter of 2025 included \$1.3 million of non-cash stock expenses, compared to \$0.6 million for the first quarter of 2024.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2025 was \$11.2 million, or \$0.19 per share, compared to a net loss of \$10.9 million, or \$0.33 per share, in the first quarter of 2024. Net loss for the first quarter of 2025 included \$2.0 million of non-cash stock expenses, compared to \$1.1 million for the first quarter of 2024.

About UNLOXCYT™ (cosibelimab-ipdl)

UNLOXCYT is a human immunoglobulin G1 monoclonal antibody that binds PD-L1 and blocks the interaction between PD-L1 and its T cell receptors, PD-1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the anti-tumor immune response. UNLOXCYT has also been shown to induce antibody-dependent cell-mediated cytotoxicity.

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

UNLOXCYT (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. 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, toxic epidermal necrolysis, and drug rash with eosinophilia and systemic symptoms, 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 (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

Please see full [Prescribing Information](#).

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. 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 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 Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended, that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, express or implied, statements regarding the Merger and related matters, including the benefits of and timeline for closing the Merger, any payments under the CVRs, prospective performance and opportunities, post-closing operations and the outlook for the companies’ businesses; projections of or targets for revenues, costs, income (or loss), earnings per share, capital expenditures, dividends, capital structure, net financials and other financial measures; expectations for the timing and commercial launch and availability of 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; the commercial potential of UNLOXCYT; anticipated healthcare professional and patient acceptance and use of UNLOXCYT for the FDA-approved indication; and assumptions underlying or relating to such 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 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 Checkpoint’s common stock and/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 Checkpoint’s business, operations, supply chain, patient enrollment and retention, clinical trials, strategy, goals and anticipated milestones; government-mandated or market-driven price decreases

for Checkpoint's products; the existence or introduction of competing products; reliance on information technology; Checkpoint's ability to successfully market current and new products; Checkpoint's and its 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 SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 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 set forth in this press release speak only as of the date of this press release, are made based on current beliefs and judgments, and are not predictions of actual performance. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us. We 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. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law. This press release and prior releases are available at www.checkpointtx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

March 31, 2025

December 31, 2024

ASSETS

Current Assets:

Cash and cash equivalents	\$	33,042	\$	6,604
Prepaid expenses and other current assets		1,122		867
Total current assets		34,164		7,471
Total Assets	\$	34,164	\$	7,471

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

Current Liabilities:

Accounts payable and accrued expenses	\$	14,741	\$	17,465
Accounts payable and accrued expenses - related party		2,868		2,433
Common stock warrant liabilities		260		198
Total current liabilities		17,869		20,096
Total Liabilities		17,869		20,096

Commitments and Contingencies**Stockholders' Equity (Deficit)**

Common Stock (\$0.0001 par value), 175,000,000 shares authorized as of March 31, 2025 and December 31, 2024

Class A common shares, 700,000 shares issued and outstanding as of March 31, 2025 and December 31, 2024	-	-
Common shares, 83,063,733 and 53,640,422 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	8	5
Common stock issuable, 0 and 2,386,808 shares as of March 31, 2025 and December 31, 2024, respectively	-	7,638
Additional paid-in capital	398,072	350,305
Accumulated deficit	(381,785)	(370,573)
Total Stockholders' Equity (Deficit)	16,295	(12,625)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 34,164	\$ 7,471

CHECKPOINT THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended March 31,	
	2025	2024
Revenue - related party	\$ —	\$ —
Operating expenses:		
Research and development	3,788	8,497
General and administrative	7,361	2,451
Total operating expenses	11,149	10,948
Loss from operations	(11,149)	(10,948)
Other income (loss):		
Interest income	1	4
Loss on common stock warrant liabilities	(62)	—
Foreign currency exchange loss	(2)	(1)
Total other income (loss)	(63)	3
Net Loss	\$ (11,212)	\$ (10,945)
Loss per Share:		
Basic and diluted net loss per Class A common shares and common shares outstanding	\$ (0.19)	\$ (0.33)

Basic and diluted weighted average number of Class A common shares and common shares outstanding

59,823,565

32,930,977



Source: Checkpoint Therapeutics, Inc