May 15, 2023

Checkpoint Therapeutics Reports First Quarter 2023 Financial Results and Recent Corporate Highlights

FDA accepted for filing the Biologics License Application for cosibelimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma; PDUFA goal date of January 3, 2024

WALTHAM, Mass., May 15, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the first quarter ended March 31, 2023, and recent corporate highlights.

"The first quarter of 2023 began a transformative year for Checkpoint, with our January submission of a Biologics License Application ("BLA") for cosibelimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC"), followed by the FDA's acceptance of the BLA filing in March, in which they indicated that no potential filing review issues have been identified and that an advisory committee meeting to discuss the application is not currently planned," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We continue to prepare for a potential commercial launch in 2024, while simultaneously progressing active discussions with multiple third parties to evaluate potential partnerships and other types of corporate development transactions."

Mr. Oliviero continued, "If approved, based on its compelling efficacy and safety profile, we believe cosibelimab has the potential to capture significant market share in this $1.6 billion U.S. market opportunity through positioning as a differentiated and possibly best-in-class treatment for patients with cutaneous squamous cell carcinoma."

Recent Corporate Highlights:

- Checkpoint submitted a BLA to the FDA seeking approval of cosibelimab in January 2023. In March 2023, Checkpoint announced the FDA accepted the BLA filing for cosibelimab and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned.
- In February 2023, Checkpoint completed a registered direct offering priced at-the-

market under Nasdaq rules and a concurrent private placement of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $7.5 million.
- In April 2023, Checkpoint completed another registered direct offering priced at-the-market under Nasdaq rules and a concurrent private placement of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $6.1 million.

Financial Results:

- **Cash Position**: As of March 31, 2023, Checkpoint's cash and cash equivalents totaled $4.8 million, compared to $12.1 million at December 31, 2022, a decrease of $7.3 million. Subsequent to the end of the quarter, Checkpoint raised approximately $6.1 million of gross proceeds in a registered direct offering completed in April 2023.
- **R&D Expenses**: Research and development expenses for the first quarter of 2023 were $15.8 million, compared to $14.7 million for the first quarter of 2022, an increase of $1.1 million. Research and development expenses for the first quarter of 2023 included $0.4 million of non-cash stock expenses, compared to $0.2 million for the first quarter of 2022.
- **G&A Expenses**: General and administrative expenses for the first quarter of 2023 were $2.3 million, compared to $2.2 million for the first quarter of 2022, an increase of $0.1 million. General and administrative expenses for the first quarter of 2023 and 2022 both included $0.7 million of non-cash stock expenses.
- **Net Loss**: Net loss attributable to common stockholders for the first quarter of 2023 was $10.5 million, or $0.89 per share, compared to a net loss of $16.8 million, or $1.98 per share, in the first quarter of 2022. Net loss for the first quarter of 2023 included $1.1 million of non-cash stock expenses, compared to $0.9 million for the first quarter of 2022.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead antibody product candidate, cosibelimab, a potential best-in-class anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing open-label, multi-regional, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including cohorts in metastatic and locally advanced cSCC intended to support one or more applications for marketing approval. Based on positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint submitted a BLA for these indications in January 2023, which application is filed and under review with a PDUFA goal date of January 3, 2024. Checkpoint is evaluating its lead 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, statements regarding the FDA review of the BLA for the approval of cosibelimab for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation and the commercial potential of cosibelimab if the BLA is approved, statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, the two-fold mechanism of action of cosibelimab translating into potential enhanced efficacy, and our projections of publication and regulatory review timelines. Factors that could cause our actual results to differ materially include the following: the risk that topline and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline or interim data we previously published; the risk that safety issues or trends will be observed in the clinical trial when the full safety dataset is available and analyzed; the risk that a positive primary endpoint does not translate to all, or any, secondary endpoints being met; risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the Phase 1 clinical trial; the risk that the clinical results from the Phase 1 clinical trial will not support regulatory approval of cosibelimab to treat cSCC or, if approved, that cosibelimab will not be commercially successful; risks related to our chemistry, manufacturing and controls and contract manufacturing relationships; risks related to our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks related to our need for substantial additional funds; other uncertainties inherent in research and development; our dependence on third-party suppliers; government regulation; patent and intellectual property matters; competition; unfavorable market or other economic conditions; and our ability to achieve the milestones we project, including the risk that the evolving and unpredictable Russia/Ukraine conflict and COVID-19 pandemic delay achievement of those milestones. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K, and in our other filings with the U.S. Securities and Exchange Commission. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

Any forward-looking statements set forth in this press release speak only as of the date of this press release. 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.

Company Contact:
Jaclyn Jaffe
Checkpoint Therapeutics, Inc.
(781) 652-4500
ir@checkpointtx.com

Investor Relations Contact:
Ashley R. Robinson
Managing Director, LifeSci Advisors, LLC
(617) 430-7577
arr@lifesciadvisors.com

Media Relations Contact:
Katie Kennedy
Gregory FCA
610-731-1045
Checkpoint@gregoryfca.com

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

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,846	$ 12,068
Prepaid expenses and other current assets	1,015	1,149
Other receivables - related party	35	73
Total current assets	5,896	13,290
Total Assets	**$ 5,896**	**$ 13,290**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 22,620	$ 20,297
Accounts payable and accrued expenses - related party	1,851	1,306
Common stock warrant liabilities	3,604	11,170
Total current liabilities	28,075	32,773
Total Liabilities	**28,075**	**32,773**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 50,000,000 shares authorized as of March 31, 2023 and December 31, 2022		
Class A common shares, 700,000 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Common shares, 13,201,070 and 9,586,683 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	1	1
Common stock issuable, 0 and 368,907 shares as of March 31, 2023 and December 31, 2022, respectively	-	1,885
Additional paid-in capital	250,780	241,117
Accumulated deficit	(272,960)	(262,486)
Total Stockholders' (Deficit) Equity	(22,179)	(19,483)
Total Liabilities and Stockholders' (Deficit) Equity	**$ 5,896**	**$ 13,290**

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

	For the three months ended March 31,	
	2023	2022
Revenue - related party	$ 35	$ 52
Operating expenses:		
Research and development	15,826	14,670
General and administrative	2,292	2,243
Total operating expenses	18,118	16,913
Loss from operations	(18,083)	(16,861)
Other income:		
Interest income	43	13
Gain on common stock warrant liabilities	7,566	-
Total other income	7,609	13
Net Loss	**$ (10,474)**	**$ (16,848)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (0.89)	$ (1.98)
Basic and diluted weighted average number of common shares outstanding	11,749,139	8,504,989

Checkpoint Therapeutics

Source: Checkpoint Therapeutics, Inc