August 14, 2023

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

Biologics License Application for cosibelimab under review by U.S. FDA; Successful mid-cycle meeting with U.S. FDA completed; PDUFA goal date of January 3, 2024

Longer-term cosibelimab results demonstrate substantial increases in complete response rates and continued favorable safety profile in advanced cutaneous squamous cell carcinoma

Unique potential for cosibelimab to address a large unmet clinical need in immunosuppressed and high risk patients

WALTHAM, Mass., Aug. 14, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the second quarter ended June 30, 2023, and recent corporate highlights.

“We continue to work with the U.S. Food and Drug Administration (“FDA”) toward the January 3, 2024 action date for our Biologics License Application (“BLA”) for cosibelimab. Recently, our mid-cycle communication meeting with the FDA was successfully completed, and the FDA noted that no significant review issues or safety concerns have been identified in their review to date,” said James Oliviero, President and Chief Executive Officer of Checkpoint.

“We are also encouraged by the recently announced longer-term data from our pivotal studies of cosibelimab in locally advanced and metastatic cutaneous squamous cell carcinoma (“cSCC”), which demonstrate a deepening of response with cosibelimab treatment over time, resulting in substantially higher complete response rates than previously reported. Specifically, complete response rates more than doubled from 10% to 23% in locally advanced cSCC and nearly doubled, from 8% to 13%, in metastatic cSCC,” continued Oliviero. “We believe cosibelimab’s unique dual mechanism of action will benefit not just immunocompetent patients, but also the large number of difficult-to-treat patients with immunosuppressive conditions or taking immunosuppressive medications who are in need of more effective treatment options than available today.”

“Equally important, longer-term results continue to confirm cosibelimab's favorable safety

profile, with only 2% of patients experiencing a severe immune-related adverse event ("irAE") and only 1% discontinuing treatment because of an irAE, substantially lower rates than observed with currently approved immunotherapies. We believe cosibelimab's favorable safety profile should position the product as the preferred immunotherapy of oncologists for high-risk patients, such as those with solid organ transplants or autoimmune disease, upon its potential launch early next year," concluded Oliviero.

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 April, May and July 2023, Checkpoint completed registered direct offerings priced at-the-market under Nasdaq rules for total gross proceeds of approximately $26.1 million.
- In June 2023, Checkpoint announced that new pharmacokinetic modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented at the Population Approach Group Europe 2023 annual meeting. Results support the comparability of cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens.
- In July 2023, Checkpoint announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cSCC. These results demonstrate a deepening of response with cosibelimab treatment over time, resulting in substantially higher complete response rates than previously reported. Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either the locally advanced or metastatic cSCC group.

Financial Results:

- **Cash Position**: As of June 30, 2023, Checkpoint's cash and cash equivalents totaled $7.4 million, compared to $4.8 million at March 31, 2023 and $12.1 million at December 31, 2022, an increase of $2.6 million for the quarter and a decrease of $4.7 million for the first half of 2023. Subsequent to the end of the second quarter, Checkpoint raised approximately $10.0 million of gross proceeds in a registered direct offering completed in July 2023.
- **R&D Expenses**: Research and development expenses for the second quarter of 2023 were $13.9 million, compared to $12.1 million for the second quarter of 2022, an increase of $1.8 million. Research and development expenses for the second quarter of 2023 primarily consisted of $9.9 million related to commercial manufacturing costs and inventory build for cosibelimab to support a potential 2024 launch.
- **G&A Expenses**: General and administrative expenses for the second quarter of 2023 were $2.3 million, compared to $2.1 million for the second quarter of 2022, an increase of $0.2 million. General and administrative expenses for the second quarter of 2023 included $0.8 million of non-cash stock expenses, compared to $0.5 million for the second quarter of 2022.
- **Net Loss**: Net loss attributable to common stockholders for the second quarter of 2023 was $16.5 million, or $1.05 per share, compared to a net loss of $14.1 million, or $1.62

per share, in the second quarter of 2022. Net loss for the second quarter of 2023 included $1.0 million of non-cash stock expenses, compared to $0.7 million for the second 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.

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

	June 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,421	$ 12,068
Prepaid expenses and other current assets	886	1,149
Other receivables - related party	31	73
Total current assets	8,338	13,290
Total Assets	**$ 8,338**	**$ 13,290**

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 25,194	$ 20,297
Accounts payable and accrued expenses - related party	2,453	1,306
Common stock warrant liabilities	3,961	11,170
Total current liabilities	31,608	32,773
Total Liabilities	**31,608**	**32,773**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 80,000,000 and 50,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively		
Class A common shares, 700,000 shares issued and outstanding as of June 30, 2023 and December 31, 2022	-	-
Common shares, 17,238,393 and 9,586,683 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	2	1
Common stock issuable, 0 and 368,907 shares as of June 30, 2023 and December 31, 2022, respectively	-	1,885
Additional paid-in capital	266,209	241,117
Accumulated deficit	(289,481)	(262,486)
Total Stockholders' (Deficit) Equity	(23,270)	(19,483)
Total Liabilities and Stockholders' (Deficit) Equity	**$ 8,338**	**$ 13,290**

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue - related party	$ 31	$ 18	$ 66	$ 70
Operating expenses:				
Research and development	13,945	12,053	29,771	26,723
General and administrative	2,281	2,129	4,573	4,372
Total operating expenses	16,226	14,182	34,344	31,095
Loss from operations	(16,195)	(14,164)	(34,278)	(31,025)
Other income				
Interest income	31	22	74	35
(Loss) gain on common stock warrant liabilities	(357)	-	7,209	-
Total other income	(326)	22	7,283	35
Net Loss	**$ (16,521)**	**$ (14,142)**	**$ (26,995)**	**$ (30,990)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (1.05)	$ (1.62)	$ (1.97)	$ (3.59)
Basic and diluted weighted average number of common shares outstanding	15,700,324	8,750,982	13,735,646	8,628,665

Source: Checkpoint Therapeutics, Inc