August 12, 2022

Checkpoint Therapeutics Reports Second Quarter 2022 Financial Results and Recent Corporate Highlights

Positive interim results from registration-enabling study of cosibelimab in locally advanced cutaneous squamous cell carcinoma announced in June 2022

Successful completion of pre-BLA meetings in July 2022

Biologics license application ("BLA") submission for both metastatic and locally advanced cutaneous squamous cell carcinoma on track for later this year

WALTHAM, Mass., Aug. 12, 2022 (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, 2022, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "Over the past few months, we have made substantial progress towards the regulatory submission for, and potential approval of, cosibelimab for the treatment of cutaneous squamous cell carcinoma ("cSCC"). Simultaneously, we continue to generate compelling clinical data with cosibelimab, most recently announcing positive interim results from our registration-enabling trial in locally advanced cSCC, with over half of the patients achieving a confirmed objective response. These impressive data follow the positive results reported in metastatic cSCC earlier this year. Importantly, we successfully completed our pre-BLA meetings with the FDA in July, reaching agreement on all key aspects discussed with regard to the upcoming BLA submission, including the inclusion of both the locally advanced and metastatic indications. We remain on target to submit the cosibelimab BLA in late 2022."

Mr. Oliviero, continued, "Also during the quarter, we continued to advance our commercial planning to enable a successful launch upon possible approval next year, and believe our price disruptive strategy could generate substantial market share for cosibelimab in the U.S. In parallel, we continue to engage in active discussions with multiple pharmaceutical companies with the goal of expanding access to cosibelimab to patients outside of the U.S."

Recent Corporate Highlights:

- In May 2022, Checkpoint announced that it received Pediatric Investigation Plan product-specific waivers from the European Medicines Agency and the U.K. Medicines & Healthcare products Regulatory Agency for cosibelimab in cSCC. The waivers remove the requirement to conduct pediatric clinical studies to support cosibelimab marketing authorization applications in Europe.

- In June 2022, the top-line results of the pivotal trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights presented include a confirmed objective response rate ("ORR") by independent central review in the modified intent to treat population of 48.7% (95% CI, 37.0-60.4) and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals.
- Also in June 2022, Checkpoint announced positive interim results from its pivotal trial of cosibelimab in locally advanced cSCC. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7), substantially exceeding a clinically meaningful lower bound of the 95% two-sided confidence interval.
- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls [CMC] and clinical/non-clinical). Based upon favorable interactions with the agency, the planned BLA submission will include both the metastatic and locally advanced indications. Checkpoint also reached agreement with the FDA on all key aspects discussed with regard to the content of the upcoming BLA submission.
- Checkpoint is discontinuing its CONTERNO study, a global, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-squamous non-small cell lung cancer, due to the substantially longer enrollment period expected as a result of the ongoing conflict in Ukraine. The Company expects that the study will be wound down and closed over the coming months and all costs associated with the study to cease by the end of the fourth quarter.

Financial Results:

- **Cash Position**: As of June 30, 2022, Checkpoint's cash and cash equivalents totaled $30.9 million, compared to $41.5 million at March 31, 2022 and $54.7 million at December 31, 2021, a decrease of $10.6 million for the quarter and a decrease of $23.8 million for the first half of 2022.
- **R&D Expenses**: Research and development expenses for the second quarter of 2022 were $12.1 million, compared to $7.2 million for the second quarter of 2021, an increase of $4.9 million. Research and development expenses for the second quarters of 2022 and 2021 each included $0.2 million of non-cash stock expenses.
- **G&A Expenses**: General and administrative expenses for the second quarters of 2022 and 2021 each were $2.1 million. General and administrative expenses for the second quarter of 2022 included $0.5 million of non-cash stock expenses, compared to $0.9 million for the second quarter of 2021.
- **Net Loss**: Net loss attributable to common stockholders for the second quarter of 2022 was $14.1 million, or $0.16 per share, compared to a net loss of $9.1 million, or $0.12 per share, in the second quarter of 2021. Net loss for the second quarter of 2022 included $0.7 million of non-cash stock expenses, compared to $1.0 million for the second quarter of 2021.

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 global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma ("cSCC") intended to support one or more applications for marketing approval. Following positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint intends to submit a Biologics License Application for these indications later this year. 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 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, projections of publication and regulatory submission timelines, and our planned price disruptive strategy generating substantial market share for cosibelimab in the U.S. Factors that could cause our actual results to differ materially include the following: our ability to successfully deliver the complete dataset from the clinical trial and complete a BLA submission on schedule as planned; 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 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; 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 for the fiscal year ended December 31, 2021 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.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 30,887	$ 54,735
Prepaid expenses and other current assets	1,178	976
Other receivables - related party	18	17
Total current assets	32,083	55,728
Total Assets	**$ 32,083**	**$ 55,728**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 23,496	$ 24,919

Accounts payable and accrued expenses - related party	1,125	1,063
Total current liabilities	24,621	25,982
Total Liabilities	**24,621**	**25,982**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 135,000,000 shares authorized as of June 30, 2022 and December 31, 2021		
Class A common shares, 7,000,000 shares issued and outstanding as of June 30, 2022 and December 31, 2021	1	1
Common shares, 84,905,751 and 77,574,405 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	8	8
Common stock issuable, 0 and 2,121,422 shares as of June 30, 2022 and December 31, 2021, respectively	-	6,598
Additional paid-in capital	238,305	223,001
Accumulated deficit	(230,852)	(199,862)
Total Stockholders' Equity	7,462	29,746
Total Liabilities and Stockholders' Equity	**$ 32,083**	**$ 55,728**

CHECKPOINT THERAPEUTICS, INC.
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,	
	2022	**2021**	**2022**	**2021**
Revenue - related party	$ 18	$ 155	$ 70	$ 223
Operating expenses:				
Research and development	12,053	7,198	26,723	11,411
General and administrative	2,129	2,114	4,372	4,487
Total operating expenses	14,182	9,312	31,095	15,898
Loss from operations	(14,164)	(9,157)	(31,025)	(15,675)
Other income				
Interest income	22	13	35	26
Total other income	22	13	35	26

Net Loss	**$ (14,142)**	**$ (9,144)**	**$ (30,990)**	**$ (15,649)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.16)	$ (0.12)	$ (0.36)	$ (0.21)
Basic and diluted weighted average number of common shares outstanding	87,509,824	75,492,853	86,286,655	72,912,456

Source: Checkpoint Therapeutics, Inc