August 5, 2021

Checkpoint Therapeutics Reports Second Quarter 2021 Financial Results

NEW YORK, Aug. 05, 2021 (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, 2021.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, "In the second quarter of 2021, we were pleased to announce the completion of enrollment in our pivotal cohort of patients with metastatic cutaneous squamous cell carcinoma ("cSCC") in our ongoing registration-enabling clinical trial for cosibelimab, our potential best-in-class anti-PD-L1 antibody product candidate, and continue to expect to report top-line data in the fourth quarter of this year. Upon a successful outcome, Checkpoint intends to submit a Biologics License Application ("BLA") for cosibelimab in 2022, followed shortly thereafter by a Marketing Authorization Application submission in Europe. With a potential favorable safety profile and a plan to commercialize at a substantially lower price than currently available therapies in this drug class, we believe cosibelimab could be a disruptive product in the $25 billion and growing PD-(L)1 market."

Mr. Oliviero continued, "Additionally, during the second quarter, we had productive interactions with the FDA regarding our development program for olafertinib (formerly CK-101), our third-generation epidermal growth factor receptor ("EGFR") inhibitor being evaluated by our partner in an ongoing double-blind, randomized Phase 3 study in China. We intend to utilize the Phase 3 study, if successful, to support a New Drug Application ("NDA") submission for olafertinib as a potential first-line treatment for patients with non-small cell lung cancer whose tumors have certain types of EGFR mutations."

Financial Results:

- **Cash Position**: As of June 30, 2021, Checkpoint's cash and cash equivalents totaled $65.1 million, compared to $60.0 million at March 31, 2021 and $40.8 million at December 31, 2020, an increase of $5.1 million for the quarter and an increase of $24.3 million for the first half of 2021.
- **R&D Expenses**: Research and development expenses for the second quarter of 2021 were $7.2 million, compared to $3.0 million for the second quarter of 2020, an increase of $4.2 million. The increase in research and development expense is primarily attributable to an increase in clinical trial and manufacturing related expenses for cosibelimab. Research and development expenses for the second quarters of 2021 and 2020 each included $0.2 million of non-cash stock expenses.

- **G&A Expenses**: General and administrative expenses for the second quarter of 2021 were $2.1 million, compared to $1.7 million for the second quarter of 2020, an increase of $0.4 million. General and administrative expenses for the second quarter of 2021 included $0.9 million of non-cash stock expenses, compared to $0.7 million for the second quarter of 2020.
- **Net Loss**: Net loss attributable to common stockholders for the second quarter of 2021 was $9.1 million, or $0.12 per share, compared to a net loss of $4.6 million, or $0.09 per share, in the second quarter of 2020. Net loss for the second quarter of 2021 included $1.0 million of non-cash stock expenses, compared to $0.8 million for the second quarter of 2020.

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 intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, 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 New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release may contain "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. Such statements include, but are not limited to, any statements relating to our plans to submit one or more Biologics License Applications and seek approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy, product development programs and commercial prospects, and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to our growth strategy and commercial prospects; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development;

our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our Securities and Exchange Commission filings. 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Company Contacts:
Jaclyn Jaffe and Bill Begien
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:
Eddie Kraft
Gregory FCA
(212) 398-9680
ekraft@gregoryfca.com

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

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 65,124	$ 40,772
Prepaid expenses and other assets	844	1,804
Other receivables - related party	155	20
Total current assets	66,123	42,596
Total Assets	**$ 66,123**	**$ 42,596**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 8,346	$ 6,367
Accounts payable and accrued expenses - related party	903	850
Total current liabilities	9,249	7,217
Total Liabilities	**9,249**	**7,217**
Commitments and Contingencies		

Stockholders' Equity		
Common Stock ($0.0001 par value), 135,000,000 and 95,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively		
Class A common shares, 7,000,000 shares issued and outstanding as of June 30, 2021 and December 31, 2020	1	1
Common shares, 75,741,873 and 62,420,439 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	8	6
Common stock issuable, 0 and 1,742,449 shares as of June 30, 2021 and December 31, 2020, respectively	-	4,617
Additional paid-in capital	215,706	173,947
Accumulated deficit	(158,841)	(143,192)
Total Stockholders' Equity	56,874	35,379
Total Liabilities and Stockholders' Equity	**$ 66,123**	**$ 42,596**

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,	
	2021	**2020**	**2021**	**2020**
Revenue - related party	$ 155	$ 42	$ 223	$ 1,014
Operating expenses:				
Research and development	7,198	3,029	11,411	5,664
General and administrative	2,114	1,687	4,487	3,365
Total operating expenses	9,312	4,716	15,898	9,029
Loss from operations	(9,157)	(4,674)	(15,675)	(8,015)
Other income				
Interest income	13	29	26	89
Total other income	13	29	26	89
Net Loss	**$ (9,144)**	**$ (4,645)**	**$ (15,649)**	**$ (7,926)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.12)	$ (0.09)	$ (0.21)	$ (0.15)
Basic and diluted weighted average number of common shares outstanding	75,492,853	51,802,451	72,912,456	51,338,963

CHECKPOINT THERAPEUTICS

Source: Checkpoint Therapeutics, Inc