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

Positive top-line results from registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma announced in January 2022; BLA submission expected in 2022

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

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "The positive topline results generated in the first quarter from our ongoing registrational trial of cosibelimab in metastatic cutaneous squamous cell carcinoma ("cSCC") laid the foundation for a potentially transformational year for our lead immunotherapy product candidate and for our company as a whole. We remain on track to submit our U.S. Biologics License Application ("BLA") for cosibelimab later this year and continue to evaluate partnership opportunities for the potential commercialization of cosibelimab in Europe and other key territories worldwide." Mr. Oliviero continued, "Our focus remains on advancing our pipeline of potentially life-saving novel oncology therapies with the goal of expanding patient access globally through a disruptive pricing strategy, beginning with the \$30 billion and growing PD-(L)1 market."

Recent Corporate Highlights:

- In January 2022, Checkpoint announced positive topline results from the ongoing registration-enabling clinical trial evaluating the safety and efficacy of its anti-PD-L1 antibody, cosibelimab, administered as a fixed dose of 800 mg every two weeks in patients with metastatic cSCC. The study met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 criteria. Checkpoint intends to submit a BLA for cosibelimab in late 2022, followed by a Marketing Authorization Application submission in Europe and other territories worldwide. With a potentially favorable safety profile versus anti-PD-1 therapy and a

plan to commercialize at a substantially lower price, Checkpoint believes cosibelimab has the potential to be a market disruptive product in the \$30 billion and growing PD-(L)1 class.

- In April 2022, Checkpoint announced that the results of its pivotal trial of cosibelimab in cSCC were selected for poster presentation at the 2022 American Society of Clinical Oncology Annual Meeting, to be held at McCormick Place, in Chicago, June 3-7, 2022.

Financial Results:

- **Cash Position:** As of March 31, 2022, Checkpoint's cash and cash equivalents totaled \$41.5 million, compared to \$54.7 million at December 31, 2021, a decrease of \$13.2 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2022 were \$14.7 million, compared to \$4.2 million for the first quarter of 2021, an increase of \$10.5 million. Research and development expenses for the first quarters of 2022 and 2021 each included \$0.2 million of non-cash stock expenses.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2022 were \$2.2 million, compared to \$2.4 million for the first quarter of 2021, a decrease of \$0.2 million. General and administrative expenses for the first quarter of 2022 included \$0.7 million of non-cash stock expenses, compared to \$1.2 million for the first quarter of 2021.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2022 was \$16.8 million, or \$0.20 per share, compared to a net loss of \$6.5 million, or \$0.09 per share, in the first quarter of 2021. Net loss for the first quarter of 2022 included \$0.9 million of non-cash stock expenses, compared to \$1.4 million for the first 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 results in metastatic cSCC, Checkpoint intends to submit a Biologics License Application for this indication 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, and projections of publication and regulatory submission timelines. 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 data remains subject to audit and verification procedures that may result in the final data being materially different from the topline 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)

	<u>March 31, 2022</u>	<u>December 31,</u>
	<u>(Unaudited)</u>	<u>2021</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 41,476	\$ 54,735
Prepaid expenses and other assets	1,378	976
Other receivables - related party	52	17
Total current assets	<u>42,906</u>	<u>55,728</u>
Total Assets	\$ 42,906	\$ 55,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 21,675	\$ 24,919
Accounts payable and accrued expenses - related party	1,015	1,063
Total current liabilities	<u>22,690</u>	<u>25,982</u>
Total Liabilities	<u>22,690</u>	<u>25,982</u>
Commitments and Contingencies		
Stockholders' Equity		
Common Stock (\$0.0001 par value), 135,000,000 shares authorized as of March 31, 2022 and December 31, 2021		
Class A common shares, 7,000,000 shares issued and outstanding as of March 31, 2022 and December 31, 2021	1	1
Common shares, 83,801,242 and 77,574,405 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	8	8
Common stock issuable, 0 and 2,121,422 shares as of March 31, 2022 and December 31, 2021, respectively	-	6,598
Additional paid-in capital	236,917	223,001
Accumulated deficit	(216,710)	(199,862)
Total Stockholders' Equity	<u>20,216</u>	<u>29,746</u>
Total Liabilities and Stockholders' Equity	\$ 42,906	\$ 55,728

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

For the three months ended
March 31,

	2022	2021
Revenue - related party	\$ 52	\$ 68
Operating expenses:		
Research and development	14,670	4,213
General and administrative	2,243	2,373
Total operating expenses	16,913	6,586
Loss from operations	(16,861)	(6,518)
Other income		
Interest income	13	13
Total other income	13	13
Net Loss	\$ (16,848)	\$ (6,505)
Loss per Share:		
Basic and diluted net loss per common share outstanding	\$ (0.20)	\$ (0.09)
Basic and diluted weighted average number of common shares outstanding	85,049,895	70,303,387



Source: Checkpoint Therapeutics, Inc