March 28, 2022

Checkpoint Therapeutics Reports Full-Year 2021 Financial Results and Recent Corporate Highlights

WALTHAM, Mass., March 28, 2022 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the full-year ended December 31, 2021 and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “The past year represented a truly transformational period for Checkpoint Therapeutics, with the foundation laid for multiple significant potentially value enhancing catalysts in 2022. Following the positive topline results from our ongoing registrational trial of cosibelimab in metastatic cutaneous squamous cell carcinoma announced earlier this year, we look forward to a planned Biologics License Application submission for cosibelimab later in 2022.” Mr. Oliviero continued, “We remain focused on expeditiously advancing our pipeline of product candidates with the goal of expanding patient access globally to potentially life-saving novel oncology therapies through a disruptive pricing strategy.”

2021 and 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 cutaneous squamous cell carcinoma (“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 Biologics License Application 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 December 2021, Checkpoint announced the initiation of the 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.

- During the second quarter of 2021, Checkpoint had productive interactions with the FDA regarding its ongoing development program for olafertinib (formerly CK-101), a third-generation epidermal growth factor receptor inhibitor being evaluated by its partner in an ongoing double-blind, randomized Phase 3 study in China.
- In March 2021, Checkpoint announced the formation of a Scientific Advisory Board comprised of clinical and scientific thought leaders in oncology. Members include Wayne A. Marasco, M.D., Ph.D., F. Stephen Hodi, Jr., M.D., Bruce E. Johnson, M.D., Roy S. Herbst, M.D., Ph.D., David Miller, M.D., Ph.D., and Emily Ruiz, M.D., M.P.H.

Financial Results:

- **Cash Position**: As of December 31, 2021, Checkpoint's cash and cash equivalents totaled $54.7 million, compared to $40.8 million at December 31, 2020, an increase of $13.9 million.
- **R&D Expenses**: Research and development expenses for the year ended December 31, 2021, were $48.5 million, compared to $16.4 million for the year ended December 31, 2020, an increase of $32.1 million. Research and development expenses for the year ended December 31, 2021 included $7.3 million of non-cash stock expenses, compared to $5.2 million in non-cash stock expenses for the year ended December 31, 2020.
- **G&A Expenses**: General and administrative expenses for the year ended December 31, 2021 were $8.5 million, compared to $7.9 million for the year ended December 31, 2020, an increase of $0.6 million. General and administrative expenses for the year ended December 31, 2021 included $3.5 million of non-cash stock expenses, compared to $3.1 million in non-cash stock expenses for the year ended December 31, 2020.
- **Net Loss**: Net loss attributable to common stockholders for the year ended December 31, 2021 was $56.7 million, or $0.75 per share, compared to a net loss of $23.1 million, or $0.41 per share, for the year ended December 31, 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 ("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)

	December 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 54,735	$ 40,772
Prepaid expenses and other assets	976	1,804
Other receivables - related party	17	20
Total current assets	55,728	42,596
Total Assets	**$ 55,728**	**$ 42,596**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 24,919	$ 6,367
Accounts payable and accrued expenses - related party	1,063	850
Total current liabilities	25,982	7,217
Total Liabilities	**25,982**	**7,217**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 135,000,000 and 95,000,000 shares authorized as of December 31, 2021 and 2020, respectively		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2021 and December 31, 2020	1	1
Common shares, 77,574,405 and 62,420,439 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	8	6
Common stock issuable, 2,121,422 and 1,742,449 shares as of December 31, 2021 and December 31, 2020, respectively	6,598	4,617
Additional paid-in capital	223,001	173,947
Accumulated deficit	(199,862)	(143,192)
Total Stockholders' Equity	29,746	35,379
Total Liabilities and Stockholders' Equity	**$ 55,728**	**$ 42,596**

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

	For the year ended December 31,	
	2021	2020
	(Unaudited)	
Revenue - related party	$ 268	$ 1,069
Operating expenses:		
Research and development	48,453	16,352
General and administrative	8,538	7,918
Total operating expenses	56,991	24,270
Loss from operations	(56,723)	(23,201)
Other income:		
Interest income	53	120
Total other income	53	120
Net Loss	**$ (56,670)**	**$ (23,081)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (0.75)	$ (0.41)
Basic and diluted weighted average number of common shares outstanding	76,031,595	55,830,582

Source: Checkpoint Therapeutics, Inc