March 9, 2021

Checkpoint Therapeutics Reports Full-Year 2020 Financial Results and Recent Corporate Highlights

NEW YORK, March 09, 2021 (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, 2020 and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We are very pleased with our momentum throughout 2020, solidifying the registration path for cosibelimab in metastatic cutaneous squamous cell carcinoma ("mCSCC"), as well as announcing positive interim data from our pivotal Phase 1 program. Checkpoint's registration-enabling study in mCSCC is approximately 90% enrolled, with full enrollment anticipated shortly. We remain on track to report full top-line results in the second half of 2021. With a potentially favorable safety profile and plan to commercialize at a lower net price, we believe cosibelimab, if approved, has the potential to be a market disruptive product in the $25 billion and growing PD-(L)1 class. We look forward to a transformative year as we continue our progress towards our first BLA submission with the U.S. Food and Drug Administration ("FDA") for cosibelimab in 2022."

2020 and Recent Corporate Highlights:

- In January 2020, Checkpoint announced confirmation of the registration path for cosibelimab in mCSCC. FDA feedback supports the plan to submit a BLA based on data from the ongoing Phase 1 clinical trial.
- In April 2020, Checkpoint announced that the U.S. Patent and Trademark Office issued a composition of matter patent for cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.
- In September 2020, at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, Checkpoint announced updated positive interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of cosibelimab in patients with advanced cancers, including the registration-enabling cohort of patients with mCSCC. Cosibelimab demonstrated a 51.4% objective response rate ("ORR") and 13.5% complete response rate, which was nearly double the complete response rate observed at the time of the previous analysis.
- Also in September 2020, Checkpoint closed on gross total proceeds of approximately $20.5 million in an underwritten public offering of its common stock, before deducting underwriting discounts and commissions and other offering-related expenses.
- In November 2020, Checkpoint's collaboration partner in Asia for CK-101, Neupharma

Inc., initiated a Phase 3, registration-enabling study of CK-101 in first-line, EGFR mutation-positive locally advanced or metastatic non-small cell lung cancer ("NSCLC"). Checkpoint plans to meet with the FDA to discuss the ongoing Phase 3 study design and its potential use, upon a successful study, to support a new drug application submission in the United States.

- Also in November 2020, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab.
- Also in November 2020, Checkpoint announced updated interim results from the ongoing global, open-label, multicohort Phase 1 clinical trial of cosibelimab in patients with advanced cancers, including a cohort of patients with previously untreated high PD-L1 expressing advanced NSCLC. The updated interim results were presented in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting held virtually. Cosibelimab demonstrated a 44.0% ORR and 10.3-month median progression-free survival in the NSCLC cohort. A Phase 3 registration-enabling trial is planned in first-line metastatic NSCLC.
- In March 2021, Checkpoint announced the formation of a Scientific Advisory Board comprised of industry thought leaders. Members include Wayne A. Marasco, M.D., Ph.D., F. Stephen Hodi, Jr., M.D., Bruce E. Johnson, M.D., David Miller, M.D., Ph.D., and Emily Ruiz, M.D., M.P.H.

Financial Results:

- **Cash Position**: As of December 31, 2020, Checkpoint's cash and cash equivalents totaled $40.8 million, compared to $26.1 million at December 31, 2019, an increase of $14.7 million. Cash and cash equivalents as of December 31, 2020 does not include approximately $12.0 million of net proceeds from the utilization of the Company's At-the-Market Issuance Sales Agreement during the first quarter of 2021 at an average price of $3.88.
- **R&D Expenses**: Research and development expenses for the year ended December 31, 2020, were $16.4 million, compared to $19.3 million for the year ended December 31, 2019, a decrease of $2.9 million. Research and development expenses for the year ended December 31, 2020 included $5.2 million of non-cash stock expenses, compared to $3.2 million in non-cash stock expenses for the year ended December 31, 2019.
- **G&A Expenses**: General and administrative expenses for the year ended December 31, 2020 were $7.9 million, compared to $7.2 million for the year ended December 31, 2019, an increase of $0.7 million. General and administrative expenses for the year ended December 31, 2020 included $3.1 million of non-cash stock expenses, compared to $3.2 million in non-cash stock expenses for the year ended December 31, 2019.
- **Net Loss**: Net loss attributable to common stockholders for the year ended December 31, 2020 was $23.1 million, or $0.41 per share, compared to a net loss of $24.7 million, or $0.70 per share, for the year ended December 31, 2019.

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.

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

	December 31,	
	2020	**2019**
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 40,772	$ 26,077
Prepaid expenses and other assets	1,804	863
Other receivables - related party	20	26
Total current assets	42,596	26,966
Total Assets	**$ 42,596**	**$ 26,966**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 6,367	$ 7,257
Accounts payable and accrued expenses - related party	850	862
Total current liabilities	7,217	8,119
Total Liabilities	**7,217**	**8,119**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 95,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2020 and December 31, 2019	1	1
Common shares, 62,420,439 and 47,004,764 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	6	5

Common stock issuable, 1,742,449 and 1,459,305 shares as of December 31, 2020 and December 31, 2019, respectively	4,617	2,510
Additional paid-in capital	173,947	136,442
Accumulated deficit	(143,192)	(120,111)
Total Stockholders' Equity	35,379	18,847
Total Liabilities and Stockholders' Equity	**$ 42,596**	**$ 26,966**

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

	For the year ended December 31,	
	2020	**2019**
	(Unaudited)	
Revenue - related party	$ 1,069	$ 1,708
Operating expenses:		
Research and development	16,352	19,325
General and administrative	7,918	7,233
Total operating expenses	24,270	26,558
Loss from operations	(23,201)	(24,850)
Other income:		
Interest income	120	136
Total other income	120	136
Net Loss	**$ (23,081)**	**$ (24,714)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (0.41)	$ (0.70)
Basic and diluted weighted average number of common shares outstanding	55,830,582	35,303,955

CHECKPOINT THERAPEUTICS

Source: Checkpoint Therapeutics, Inc