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Checkpoint Therapeutics Reports First Quarter 2020 Financial Results and Recent Corporate Highlights

NEW YORK, May 06, 2020 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced financial results for the first quarter ended March 31, 2020, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "In the first quarter of 2020, we continued to make progress with the development of cosibelimab, our lead antibody product candidate that is poised to be a potentially differentiated treatment from currently marketed PD-1 and PD-L1 antibodies. As announced in January, the U.S. Food and Drug Administration ("FDA") confirmed the registration submission pathway for cosibelimab in its initial indication of metastatic cutaneous squamous cell carcinoma ("CSCC") based on the ongoing multicenter Phase 1 clinical trial. We look forward to reporting additional interim data from this clinical trial later this year. Additionally, we recently announced that the U.S. Patent and Trademark Office issued a composition of matter patent for cosibelimab, which provides broad, foundational composition of matter protection for our antibody through at least May 2038. With these developments, we look forward to continuing to enroll CSCC patients in order to support our first marketing application submission based on this ongoing clinical trial."

Recent Corporate Highlights:

- In January 2020, Checkpoint announced confirmation of the registration path for cosibelimab in metastatic CSCC. FDA feedback supports the Company's plan to submit a Biologics License Application ("BLA") based on data from the ongoing Phase 1 trial. Over one-third of enrollment is complete in the cohort of patients with metastatic CSCC.
- 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.

Financial Results:

- **Cash Position:** As of March 31, 2020, Checkpoint's cash and cash equivalents totaled \$21.5 million, compared to \$26.1 million as of December 31, 2019, a decrease of \$4.6 million.

- **Revenue:** Revenue for the first quarter of 2020 was \$1.0 million, compared to \$0.4 million for the first quarter of 2019, an increase of \$0.6 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2020 were \$2.6 million, compared to \$4.6 million for the first quarter of 2019, a decrease of \$2.0 million. Research and development expenses for the first quarter of 2020 included \$0.1 million of non-cash stock expenses, compared to \$0.2 million in the first quarter of 2019.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2020 were \$1.7 million, essentially flat as compared to the first quarter of 2019. General and administrative expenses for the first quarter of 2020 included \$0.5 million of non-cash stock expenses, compared to \$0.6 million for the first quarter of 2019.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2020 was \$3.3 million, or \$0.06 per share, compared to a net loss of \$5.9 million, or \$0.18 per share, in the first quarter of 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 potentially differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application submissions. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor (“EGFR”) inhibitor, in a Phase 1 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer (“NSCLC”). 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 BLAs 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 how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, 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; 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 SEC 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.

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

	March 31, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 21,481	\$ 26,077
Prepaid expenses and other assets	753	863
Other receivables - related party	972	26
Total current assets	23,206	26,966
Total Assets	\$ 23,206	\$ 26,966
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,839	\$ 7,257
Accounts payable and accrued expenses - related party	1,149	862

Total current liabilities	6,988	8,119
Total Liabilities	6,988	8,119

Commitments and Contingencies

Stockholders' Equity

Common Stock (\$0.0001 par value), 60,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of March 31, 2020 and December 31, 2019	1	1
Common shares, 48,038,506 and 47,004,764 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	5	5
Common stock issuable, 1,459,305 and 1,459,305 shares as of March 31, 2020 and December 31, 2019, respectively	2,510	2,510
Additional paid-in capital	137,094	136,442
Accumulated deficit	(123,392)	(120,111)
Total Stockholders' Equity	16,218	18,847
Total Liabilities and Stockholders' Equity	\$ 23,206	\$ 26,966

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

	For the three months ended March 31,	
	2020	2019
Revenue - related party	\$ 972	\$ 352
Operating expenses:		
Research and development	2,635	4,581
General and administrative	1,678	1,703
Total operating expenses	4,313	6,284
Loss from operations	(3,341)	(5,932)
Other income		
Interest income	60	42
Total other income	60	42
Net Loss	\$ (3,281)	\$ (5,890)
Loss per Share:		
Basic and diluted net loss per common share outstanding	\$ (0.06)	\$ (0.18)
Basic and diluted weighted average number of common shares outstanding	50,875,476	32,243,796



Source: Checkpoint Therapeutics, Inc