

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

NEW YORK, Nov. 04, 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 third quarter ended September 30, 2020, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "We are excited to have presented updated positive interim results from the ongoing registration-enabling clinical trial of cosibelimab for the treatment of metastatic cutaneous squamous cell carcinoma ("mCSCC") at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020. These compelling data underscore cosibelimab's potential to be best-in-class. We expect to complete enrollment of the registration-enabling cohort in mCSCC in early 2021 and anticipate reporting top-line results in the second half of the year. Based on our planned pricing strategy, we believe cosibelimab can be a market-disruptive product in the \$25 billion PD-(L)1 class. Importantly, in order to support the continued development of cosibelimab, as well as our broader oncology pipeline, we expanded our cash runway through the successful completion of a \$20.5 million financing during the third quarter."

Recent Corporate Highlights:

- In September 2020, Checkpoint announced updated positive interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of its anti-PD-L1 antibody, 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 is nearly double the complete response rate observed at the time of previous analysis. These interim data were presented at the ESMO Virtual Congress 2020.
- In September 2020, Checkpoint closed on gross total 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.
- Earlier this month, 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.

Financial Results:

- Cash Position: As of September 30, 2020, Checkpoint's cash and cash equivalents totaled \$42.0 million, compared to \$26.1 million as of December 31, 2019, an increase of \$15.9 million year-to-date.
- **R&D Expenses**: Research and development expenses for the third quarter of 2020 were \$2.5 million, compared to \$3.9 million for the third quarter of 2019, a decrease of \$1.4 million. Research and development expenses for the third quarters of 2020 and 2019 each included \$0.2 million of non-cash stock expenses.
- **G&A Expenses**: General and administrative expenses for the third quarter of 2020 were \$2.4 million, compared to \$1.6 million for the third quarter of 2019, an increase of \$0.8 million. General and administrative expenses for the third quarter of 2020 included \$1.3 million of non-cash stock expenses, compared to \$0.7 million in stock compensation expense for the third quarter of 2019.
- **Net Loss**: Net loss attributable to common stockholders for the third quarter of 2020 was \$4.9 million, or \$0.09 per share, compared to a net loss of \$5.2 million, or \$0.15 per share, in the third 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 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 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 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)

	Septen	December 31, 2019			
	(Uı				
ASSETS					
Current Assets:					
Cash and cash equivalents	\$	42,029	\$	26,077	
Prepaid expenses and other assets		588		863	
Other receivables - related party		28		26	
Total current assets		42,645		26,966	
Total Assets	\$	42,645	\$	26,966	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities:					
Accounts payable and accrued expenses	\$	5,665	\$	7,257	
Accounts payable and accrued expenses - related party		755		862	
Total current liabilities		6,420		8,119	

Total Liabilities		6,420	 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 September 30, 2020 and December 31, 2019	•	1	1
Common shares, 60,883,303 and 47,004,764 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively		6	5
Common stock issuable, 0 and 1,459,305 shares as of September 30, 2020 and			
December 31, 2019, respectively		-	2,510
Additional paid-in capital		169,185	136,442
Accumulated deficit		(132,967)	(120,111)
Total Stockholders' Equity		36,225	18,847
Total Liabilities and Stockholders' Equity	\$	42,645	\$ 26,966

CHECKPOINT THERAPEUTICS, INC. STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts) (Unaudited)

	ı	For the three months ended September 30,			For the nine months ended September 30,				
		2020		2019		2020		2019	
Revenue - related party	\$	28	\$	280	\$	1,042	\$	1,683	
Operating expenses:									
Research and development		2,543		3,894		8,207		12,595	
General and administrative		2,429		1,620		5,794		5,081	
Total operating expenses		4,972		5,514		14,001		17,676	
Loss from operations	_	(4,944)	_	(5,234)		(12,959)	_	(15,993)	
Other income									
Interest income		14		28		103		105	
Total other income		14		28		103		105	
Net Loss	\$	(4,930)	\$	(5,206)	\$	(12,856)	\$	(15,888)	
Loss per Share:									
Basic and diluted net loss per common share outstanding	\$	(0.09)	\$	(0.15)	\$	(0.24)	\$	(0.48)	
Basic and diluted weighted average number of common shares outstanding		56,405,734		34,561,844		53,040,215		33,178,567	



Source: Checkpoint Therapeutics, Inc