March 30, 2023

Checkpoint Therapeutics Reports Full-Year 2022 Financial Results and Recent Corporate Highlights

FDA accepted for filing the Biologics License Application for cosibelimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma; PDUFA goal date of January 3, 2024

WALTHAM, Mass., March 30, 2023 (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, 2022, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "The past year was a momentous one for Checkpoint, and we began 2023 with the submission of our Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval of cosibelimab, our investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation. Our BLA submission was subsequently accepted for filing and is under active review with a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024."

"This initial indication for cosibelimab represents a potential $1.6 billion U.S. market opportunity," continued Oliviero. "With its unique mechanism of action and compelling safety profile, we believe cosibelimab, if approved, would be uniquely positioned to provide an important new treatment option for cSCC patients who are currently underserved by available therapies."

2022 and Recent Corporate Highlights:

- Checkpoint submitted a BLA to the FDA seeking approval of cosibelimab in January 2023. In March 2023, the FDA accepted for filing the BLA for cosibelimab and set a PDUFA goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned.
- In January 2022, Checkpoint announced positive top-line results from its registration-enabling clinical trial evaluating the safety and efficacy of 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 ("ORR") 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.

- In May 2022, Checkpoint announced that it received Pediatric Investigation Plan product-specific waivers from the European Medicines Agency and the U.K. Medicines & Healthcare products Regulatory Agency for cosibelimab in cSCC. The waivers remove the requirement to conduct pediatric clinical studies to support cosibelimab marketing authorization applications in Europe.
- In June 2022, Checkpoint announced that the top-line results of its pivotal trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights presented included confirmed ORR by independent central review in the modified intent-to-treat population of 48.7% (95% CI, 37.0-60.4), and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals.
- Also in June 2022, Checkpoint announced positive interim results from its pivotal trial of cosibelimab in locally advanced cSCC. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7).
- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls and clinical/non-clinical). Based upon favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cSCC indications. Checkpoint also reached agreement with the FDA on all key aspects discussed regarding the content of the BLA submission.
- In December 2022, Checkpoint completed a registered direct offering priced At-the-Market under Nasdaq rules, for total gross proceeds of approximately $7.5 million.
- In February 2023, Checkpoint completed another registered direct offering priced At-the-Market under Nasdaq rules and a concurrent private placement of two series of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $7.5 million.

Financial Results:

- **Cash Position**: As of December 31, 2022, Checkpoint's cash and cash equivalents totaled $12.1 million, compared to $54.7 million at December 31, 2021, a decrease of $42.6 million. This cash position is not reflective of the registered direct offering closed in February 2023 for total gross proceeds of approximately $7.5 million.
- **R&D Expenses**: Research and development expenses for the year ended December 31, 2022, were $49.8 million, compared to $48.5 million for the year ended December 31, 2021, an increase of $1.3 million. Research and development expenses for the year ended December 31, 2022 included $2.8 million of non-cash stock expenses, compared to $7.3 million in non-cash stock expenses for the year ended December 31, 2021.
- **G&A Expenses**: General and administrative expenses for the year ended December 31, 2022, were $8.7 million, compared to $8.5 million for the year ended December 31, 2021, an increase of $0.2 million. General and administrative expenses for the year ended December 31, 2022 included $2.5 million of non-cash stock expenses,

compared to $3.5 million in non-cash stock expenses for the year ended December 31, 2021.

- **Net Loss**: Net loss attributable to common stockholders for the year ended December 31, 2022 was $62.6 million, or $7.09 per share, compared to a net loss of $56.7 million, or $7.45 per share, for the year ended December 31, 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 open-label, multi-regional, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including cohorts in metastatic and locally advanced cSCC intended to support one or more applications for marketing approval. Based on positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint submitted a BLA for these indications in January 2023, which application is filed and under review with a PDUFA goal date of January 3, 2024. 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 regarding the FDA review of the BLA for the approval of cosibelimab for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation and the commercial potential of cosibelimab if the BLA is approved, 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 our projections of publication and regulatory review timelines. Factors that could cause our actual results to differ materially include the following: the risk that topline and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline or interim 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 chemistry, manufacturing and controls and contract manufacturing relationships; 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, 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, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,068	$ 54,735
Prepaid expenses and other assets	1,149	976
Other receivables - related party	73	17

Total current assets	13,290	55,728
Total Assets	**$ 13,290**	**$ 55,728**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 20,297	$ 24,919
Accounts payable and accrued expenses - related party	1,306	1,063
Common stock warrant liabilities	11,170	-
Total current liabilities	32,773	25,982
Total Liabilities	**32,773**	**25,982**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 50,000,000 and 13,500,000 shares authorized as of December 31, 2022 and 2021, respectively		
Class A common shares, 700,000 shares issued and outstanding as of December 31, 2022 and December 31, 2021	-	-
Common shares, 9,586,683 and 7,757,440 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	1	1
Common stock issuable, 368,907 and 212,142 shares as of December 31, 2022 and December 31, 2021, respectively	1,885	6,598
Additional paid-in capital	241,117	223,009
Accumulated deficit	(262,486)	(199,862)
Total Stockholders' (Deficit) Equity	(19,483)	29,746
Total Liabilities and Stockholders' (Deficit) Equity	**$ 13,290**	**$ 55,728**

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

	For the year ended December 31,	
	2022	**2021**
Revenue - related party	$ 192	$ 268
Operating expenses:		
Research and development	49,825	48,453
General and administrative	8,700	8,538
Total operating expenses	58,525	56,991
Loss from operations	(58,333)	(56,723)
Other income (loss):		
Interest income	160	53
Loss on common stock warrant liabilities	(4,451)	-
Total other income	(4,291)	53
Net Loss	**$ (62,624)**	**$ (56,670)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (7.09)	$ (7.45)
Basic and diluted weighted average number of common shares outstanding	8,835,521	7,603,160

Source: Checkpoint Therapeutics, Inc