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Checkpoint Therapeutics Announces Cosibelimab Longer-Term Results Demonstrating Substantial Increases in Complete Response Rates in Advanced Cutaneous Squamous Cell Carcinoma

55% objective response rate; 23% complete response rate in locally advanced cSCC

50% objective response rate; 13% complete response rate in metastatic cSCC

Cosibelimab continues to demonstrate a favorable safety profile

Biologics License Application currently under review by U.S. FDA; PDUFA goal date of January 3, 2024

WALTHAM, Mass., July 27, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cutaneous squamous cell carcinoma ("cSCC"). These results demonstrate a deepening of response over time, resulting in substantially higher complete response rates than previously reported. Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either group. Results determined by independent central review by treatment group were as follows:

Parameter[a]	**Locally Advanced cSCC (n=31)**		**Metastatic cSCC (n=78)**	
Data cutoff	Mar 2022	**Jan 2023**	Nov 2021	**Jan 2023**
Objective response rate (95% confidence interval)	55% (36%, 73%)	**55% (36%, 73%)**	47% (36%, 59%)	**50% (39%, 62%)**
Complete response rate	10%	**23%**	8%	**13%**
Partial response rate	45%	**32%**	39%	**37%**
Response ongoing	82%	**82%**	73%	**69%**
Median duration of response	Not reached	**Not reached**	Not reached	**Not reached**

[a] As assessed by independent central review.

"We are excited to see the substantial increases in the rate of patients experiencing a

complete response of their cSCC tumors with further cosibelimab treatment in both our locally advanced and metastatic pivotal trials," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We believe cosibelimab's strong efficacy and response durability are driven by its unique two-fold mechanism of action in which cosibelimab binds to PD-L1 with sustained high target tumor occupancy to reactivate the body's T-cell anti-tumor response, with the addition of a functional Fc domain to activate the body's natural killer immune cells to induce antibody-dependent cell-mediated cytotoxicity of tumor cells, resulting in a powerful one-two punch to eradicate tumors. We expect this dual mechanism of action to benefit not just immunocompetent patients, but also the large number of difficult-to-treat patients with immunosuppressive conditions or taking immunosuppressive medications who continue to suffer poor outcomes with currently available treatments."

Updated safety data across 247 patients enrolled and treated with cosibelimab in all cohorts of the ongoing study remain consistent with those previously reported, with only 2% of patients experiencing a severe immune-related adverse event ("irAE") and less than 1% of patients discontinuing treatment due to an irAE of any severity, both substantially lower than the rates observed with currently approved immunotherapies.

Mr. Oliviero continued, "Unlike PD-1 inhibitors, cosibelimab does not interrupt the body's PD-1/PD-L2 pathway, which we believe results in cosibelimab's low rates of autoimmunity. We believe cosibelimab's favorable safety profile should position the product as the preferred immunotherapy of oncologists for the large number of high-risk cSCC patients, such as those with solid organ transplants or autoimmune disease, upon its potential launch early next year. If our Biologics License Application ("BLA") is approved in the coming months, based on its unique mechanism of action and compelling efficacy and safety profile, we believe cosibelimab, as a differentiated and possibly best-in-class treatment, has the potential to become the market leading immunotherapy for patients with cSCC, which we estimate to be a $1.6 billion annual U.S. market opportunity."

In January 2023, Checkpoint submitted a BLA to the U.S. Food and Drug Administration ("FDA") seeking approval of cosibelimab as a treatment for patients with metastatic cSCC or locally advanced cSCC who are not candidates for curative surgery or radiation. The application is filed and under review with a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024.

Checkpoint plans to present these updated results at an upcoming medical conference.

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 cutaneous squamous cell carcinoma ("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 Biologics License Application ("BLA") for these indications in January 2023, which application is filed and under review with a Prescription Drug User Fee Act ("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; unfavorable market or other economic conditions; 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.

Company Contact:
Jaclyn Jaffe
Checkpoint Therapeutics, Inc.
(781) 652-4500
ir@checkpointtx.com

Investor Relations Contact:
Ashley R. Robinson
Managing Director, LifeSci Advisors, LLC
(617) 430-7577
arr@lifesciadvisors.com

Media Relations Contact:
Katie Kennedy
Gregory FCA
610-731-1045
checkpoint@gregoryfca.com

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