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Checkpoint Therapeutics Announces Publication of Cosibelimab Pivotal Trial Results in the Journal for ImmunoTherapy of Cancer

Cosibelimab is the first PD-L1–blocking antibody to demonstrate a robust, durable and clinically meaningful objective response, and a manageable safety profile, in patients with metastatic cutaneous squamous cell carcinoma

Biologics License Application review ongoing; PDUFA goal date of January 3, 2024

WALTHAM, Mass., Oct. 18, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced the publication of results from the multicenter, multiregional, pivotal trial evaluating cosibelimab, a differentiated and potential best-in-class anti-PD-L1 antibody, in patients with metastatic cutaneous squamous cell carcinoma ("cSCC"), in the *Journal for ImmunoTherapy of Cancer (JITC)*, the peer-reviewed, online journal of the Society of Immunotherapy of Cancer. The paper, entitled, "Efficacy and Safety of Cosibelimab, an Anti–PD-L1 Antibody, in Metastatic Cutaneous Squamous Cell Carcinoma" (doi:10.1136/jitc-2023-007637), describes safety and efficacy results from 78 patients with metastatic cSCC enrolled at clinical sites in eight countries.

Patients received cosibelimab 800 mg every two weeks as an intravenous infusion until disease progression or unacceptable toxicity. The study's primary endpoint was objective response rate ("ORR") assessed by independent central review using Response Evaluation Criteria in Solid Tumors, v.1.1. As of the pre-specified data cutoff date, the primary endpoint was met with highly clinically meaningful results. Median duration of response was not yet reached. The authors observed that cosibelimab treatment was associated with lower rates of severe immune-related adverse events ("irAEs") as compared with those reported for similar studies of PD-1-targeting agents, concluding that cosibelimab may address an area of unmet clinical need for effective and better tolerated treatments for patients with metastatic cSCC who are ineligible for curative surgery or radiation.

"The conclusions of the study are clear," commented Prof. Philip Clingan of Southern Medical Day Care Centre in Wollongong, Australia, Principal Investigator for this study and first author of the paper. "Cosibelimab is the first PD-L1-blocking antibody to demonstrate a robust and clinically meaningful ORR, with durable responses in participants, and a well-

tolerated safety profile in patients with metastatic cSCC. While existing PD-1-blocking antibodies are approved to treat advanced cSCC, many patients don't respond to treatment, experience severe irAEs or are simply not appropriate candidates for PD-1 therapy treatment, such as those that are immunocompromised, immunosuppressed or with preexisting autoimmune disease. There is therefore a significant need for improved therapies. Cosibelimab, if approved, would offer patients an important new treatment option through its dual activation of both innate and adaptive immunity to induce strong and durable anti-tumor responses, complemented by lower rates of severe adverse events as cosibelimab's binding to PD-L1 leaves the interaction of PD-1 and PD-L2 unaltered."

"Publication of these data expands the growing evidence supporting the efficacy and safety of cosibelimab," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We are encouraged by recently revealed longer-term data from our pivotal studies of cosibelimab, which demonstrate a deepening of response over time. We believe cosibelimab's dual mechanism of action and potential favorable safety profile should position the product as the preferred immunotherapy of oncologists for the large number of high-risk cSCC patients upon its potential launch early next year. We continue to work with the U.S. Food and Drug Administration ("FDA") toward the January 3, 2024, action date for our Biologics License Application for cosibelimab."

About Cutaneous Squamous Cell Carcinoma
Cutaneous squamous cell carcinoma is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1 million cases according to the Skin Cancer Foundation. While most cases are localized tumors amenable to curative resection, approximately 40,000 cases will become advanced, and an estimated 15,000 people will die from their disease each year. In addition to being a life-threatening disease, cSCC causes significant functional morbidities and cosmetic deformities based on tumors commonly arising in the head and neck region and invading blood vessels, nerves and vital organs such as the eye or ear.

About Cosibelimab
Cosibelimab is a potential best-in-class, high affinity, fully-human monoclonal antibody of IgG1 subtype that directly binds to programmed death ligand-1 ("PD-L1") and blocks the PD-L1 interaction with the programmed death receptor-1 ("PD-1") and B7.1 receptors. Cosibelimab's primary mechanism of action is based on the inhibition of the interaction between PD-L1 and its receptors PD-1 and B7.1, which removes the suppressive effects of PD-L1 on anti-tumor CD8+ T-cells to restore the cytotoxic T cell response. Cosibelimab is potentially differentiated from the currently marketed PD-1 and PD-L1 antibodies through sustained >99% target tumor occupancy to reactivate an antitumor immune response and the additional benefit of a functional Fc domain capable of inducing antibody-dependent cell-mediated cytotoxicity ("ADCC") for potential enhanced efficacy in certain tumor types.

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 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.

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