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Checkpoint Therapeutics Announces Cosibelimab Longer-Term Results in Advanced Cutaneous Squamous Cell Carcinoma Presented at ESMO Congress 2024

Biologics License Application currently under review by U.S. FDA; PDUFA goal date of December 28, 2024

WALTHAM, Mass., Sept. 16, 2024 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced the presentation of longer-term data from its pivotal trial of cosibelimab, its anti-programmed death ligand-1 ("PD-L1") antibody, in locally advanced and metastatic cutaneous squamous cell carcinoma ("cSCC") during the European Society for Medical Oncology ("ESMO") Congress 2024, which is taking place in Barcelona, Spain, from September 13 to 17, 2024.

Poster Presentation Title: Cosibelimab in Advanced Cutaneous Squamous Cell Carcinoma (CSCC): Longer-term Efficacy and Safety Results from Pivotal Study

"These longer-term results for cosibelimab presented at the ESMO Congress demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses, and continue to expand the evidence supporting the efficacy and safety of cosibelimab as a potential new treatment for advanced cSCC," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We look forward to our upcoming December 28, 2024, Prescription Drug User Fee Act ("PDUFA") goal date for our Biologics License Application for cosibelimab, and believe, if approved, cosibelimab's dual mechanisms of action and safety profile may position the product, over time, as the preferred immunotherapy of U.S. oncologists."

Data highlights include:

Efficacy

- With 16 months of additional follow-up since the primary analysis, cosibelimab demonstrated increasing objective response rates ("ORRs") and complete response rates per independent central review in 109 patients with advanced cSCC.
    - ORRs of 54.8% and 50.0% achieved in locally advanced and metastatic cSCC, with median follow-up durations of 24.1 and 29.3 months, respectively.
    - Results demonstrate a deepening of response over time, with complete response

rates of 25.8% and 12.8% in locally advanced and metastatic cSCC, respectively.
- Clinically meaningful durations of response ("DOR") were observed, with median DORs not yet reached in either group.

Safety

- Overall, in 192 advanced cSCC patients treated with cosibelimab, a manageable safety profile was observed, with notable low rates of treatment-emergent adverse events ("TEAEs"), severe immune-related adverse events ("irAEs"), and treatment discontinuations.
  - 3.6% of patients experienced an irAE assessed as grade 3, with no observed grade ≥4 irAEs.
  - No events of grade ≥3 pneumonitis, colitis, hepatitis, nephritis, or endocrinopathies.
  - Treatment discontinuation due to TEAEs, regardless of attribution, was observed in 12 patients (6.3%); the most common reason was COVID-19/COVID-19 pneumonia (1.6%).

A copy of the poster can be found on the Publications page of the Checkpoint Therapeutics website.

In December 2023, the U.S. Food and Drug Administration ("FDA") issued a complete response letter ("CRL") for the cosibelimab Biologics License Application ("BLA") for the treatment of patients with metastatic or locally advanced cSCC who are not candidates or curative surgery or radiation. The CRL only cited findings that arose during a multi-sponsor inspection of Checkpoint's third-party contract manufacturing organization ("CMO") as approvability issues to address in a resubmission. In July 2024, Checkpoint announced it had completed a resubmission of the BLA to the FDA for cosibelimab to potentially address the approvability issues cited in the CRL. The resubmission was accepted by the FDA as a complete response and the FDA has set a PDUFA goal date of December 28, 2024.

About Cutaneous Squamous Cell Carcinoma (cSCC)
Cutaneous Squamous Cell Carcinoma is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1.8 million cases according to the Skin Cancer Foundation. Important risk factors for cSCC include chronic ultraviolet exposure and immunosuppressive conditions. 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 this 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. The immune-suppressed population represents a challenging target in the treatment of advanced cSCC, as they present with a more aggressive disease and with a higher risk of developing immune-related toxicities from checkpoint inhibitor treatment.

About Cosibelimab
Cosibelimab is a potential differentiated, high affinity, fully-human monoclonal antibody of IgG1 subtype that directly binds to 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 high tumor target occupancy of PD-L1 to reactivate an antitumor immune response and the additional potential benefit of a functional Fc domain capable of inducing antibody-dependent cellular cytotoxicity ("ADCC") for potential enhanced efficacy.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. 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 differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, as a potential new treatment for patients with selected recurrent or metastatic cancers, including metastatic and locally advanced cSCC. Checkpoint is also evaluating its lead small-molecule, targeted anti-cancer agent, olafertinib, 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 our resubmission of our BLA for cosibelimab and review thereof, our belief that the BLA resubmission potentially addresses all the issues in the CRL, our belief about the comprehensive nature of our BLA resubmission and reaching alignment with the FDA on our cosibelimab BLA resubmission strategy, our ability to work with our third-party CMO and the FDA to adequately address the issues raised in the CRL and execute on a pathway forward for the potential marketing approval of cosibelimab, the adequacy of the responses to the inspection issues submitted to FDA by our third-party CMO, our projections of regulatory review timelines, the commercial potential of cosibelimab, if approved, and the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies and the dual mechanism of action of cosibelimab translating into potential enhanced efficacy. Factors that could cause our actual results to differ materially include the following: the risks and uncertainties associated with the regulatory review process; uncertainties regarding the timeline of FDA review of the resubmitted BLA; any inability to successfully work with the FDA to find a satisfactory solution to address any concerns in a timely manner or at all during the review process for the BLA, including any inability to provide the FDA with data, analysis or other information sufficient to support an approval of the BLA; our, and our third party CMO's, ability to adequately address the issues raised in the CRL; issues associated with any facility inspection or re-inspection of our third party CMO or otherwise during the review process for the BLA; the risk that our third-party CMO will not meet deadlines, and/or comply with applicable regulations; whether the FDA accepts the data and results as included in the BLA resubmission at levels consistent with the published results,

or at all; our ability to execute a partnering or other relationship to enable the commercialization of cosibelimab, if approved, on acceptable terms, if at all; 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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