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Checkpoint Therapeutics Announces Biologics License Application Resubmission for Cosibelimab

WALTHAM, Mass., July 02, 2024 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced it has completed the resubmission of its Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) for cosibelimab, its anti-programmed death ligand-1 (“PD-L1”) antibody, as a potential new treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma (“cSCC”) who are not candidates for curative surgery or curative radiation.

The BLA resubmission follows Checkpoint recently reaching alignment with the FDA on its BLA resubmission strategy to potentially address all approvability deficiencies outlined in the complete response letter (“CRL”) received last December, in which FDA 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 BLA resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab.

The BLA resubmission is supported by the results of Checkpoint’s studies in selected recurrent or metastatic cancers, including pivotal cohorts in metastatic and locally advanced cSCC. Safety and efficacy results from the metastatic cSCC cohort were published in October 2023 in the *Journal for ImmunoTherapy of Cancer (JITC)* (doi:10.1136/jitc-2023-007637).

Additionally, in July 2023, Checkpoint announced longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cSCC demonstrating a deepening of response over time, resulting in higher complete response rates than previously reported (55% objective response rate; 26% complete response rate in locally advanced cSCC and 50% objective response rate; 13% complete response rate in metastatic cSCC).

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 cell-mediated 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 (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 our resubmission of our BLA for cosibelimab, our belief that the BLA resubmission addresses all the issues in the CRL, our belief about the comprehensive nature of our BLA resubmission and expectations regarding the acceptance by the FDA and a decision by the FDA on our BLA, our 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 two-fold 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; whether or not the FDA will determine that the BLA resubmission is complete and acceptable for review; uncertainties regarding the timeline of FDA review of the resubmitted BLA, if accepted for review; 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 ability and our third party CMO to adequately address the issues raised in the CRL; any potential facility inspection or re-inspection that may be required regarding our third party CMO or otherwise; 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 relationship for commercialization of cosibelimab, if approved, on acceptable terms, if at all; the risk that our third-party CMO will not meet deadlines, and/or

comply with applicable regulations; 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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