December 5, 2023

Checkpoint Therapeutics Strengthens Intellectual Property Protection for Cosibelimab with New U.S. Patent Issuance

Upcoming PDUFA goal date of January 3, 2024

U.S. patent protection for cosibelimab through at least May 2038

WALTHAM, Mass., Dec. 05, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that the U.S. Patent and Trademark Office ("USPTO") has issued a new patent (U.S. Patent No. 11,834,505) covering a method of treating various cancers, including cutaneous squamous cell carcinoma ("cSCC"), through the administration of cosibelimab.

The USPTO previously issued a composition of matter patent (U.S. Patent No. 10,590,199), specifically covering cosibelimab, or a fragment thereof. Together, these patents protect Checkpoint's differentiated and potential best-in-class anti-PD-L1 antibody, cosibelimab, in the U.S. through at least May 2038, not including any potential patent term extension under the Hatch-Waxman Act.

Checkpoint's Biologics License Application ("BLA") for cosibelimab is currently under review by the U.S. Food and Drug Administration ("FDA") as a potential new treatment for patients with locally advanced and metastatic cSCC, with an upcoming Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024.

"With less than five weeks remaining before our assigned PDUFA date for cosibelimab, we look forward to cosibelimab potentially joining an approved class of immunotherapies with combined worldwide annual sales exceeding $35 billion," said James Oliviero, President and Chief Executive Officer of Checkpoint. "We believe our broad U.S. patent portfolio, expiring no earlier than May 2038, provides the potential for cosibelimab to be further developed into a market leading drug, not only in cSCC, but also in additional indications, both as a monotherapy and as the PD-L1 backbone for new combination regimens."

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 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 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; 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

Source: Checkpoint Therapeutics, Inc