January 4, 2023

Checkpoint Therapeutics Submits Biologics License Application to FDA for Cosibelimab as a Treatment for Patients with Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma

Positive and clinically meaningful pivotal clinical results announced in 2022 in both metastatic and locally advanced indications

WALTHAM, Mass., Jan. 04, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced the submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for the approval of cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic cutaneous squamous cell carcinoma ("cSCC") or locally advanced cSCC who are not candidates for curative surgery or radiation.

"This is a major milestone for Checkpoint Therapeutics, representing our first submission of a marketing application for one of our investigational medications and furthering our evolution from a development-stage company to a fully integrated commercial organization to support the potential launch of cosibelimab," said James Oliviero, President and Chief Executive Officer of Checkpoint. "cSCC is the second most common type of skin cancer in the United States. While most cases involve 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. Based on its compelling and differentiated product profile and the positive data generated to date, we believe cosibelimab has the potential to be an important treatment option for patients. Importantly, we continue to plan for cosibelimab to be positioned, upon regulatory approval, as potentially the first and only price disruptive PD-1/PD-L1 inhibitor in the U.S. market." Mr. Oliviero continued, "We want to thank the patients and their families, as well as the physicians and their research teams, who participated in our trial and contributed immensely to the advancement of cosibelimab."

The BLA submission is based on positive efficacy and safety results from Checkpoint's ongoing registration-enabling, multi-regional, multicohort clinical trial evaluating cosibelimab administered as fixed doses of either 800 mg every two weeks or 1200 mg every three weeks in patients with selected recurrent or metastatic cancers, including pivotal cohorts in metastatic and locally advanced cSCC.

In January 2022, Checkpoint announced that the metastatic cSCC cohort met its primary

endpoint, with cosibelimab demonstrating a confirmed objective response rate ("ORR") of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the cohort using Response Evaluation Criteria in Solid Tumors version 1.1 ("RECIST 1.1") criteria. In June 2022, Checkpoint announced positive interim results from its locally advanced cSCC cohort, with cosibelimab demonstrating a confirmed ORR of 54.8% (95% CI: 36.0, 72.7) based on independent central review of 31 patients enrolled in the cohort, exceeding a clinically meaningful lower bound of the 95% two-sided confidence interval of 25%. Based upon interactions with the FDA, the BLA submission includes both the metastatic and locally advanced cSCC indications.

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 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 for these indications in January 2023. 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 submission of a Biologics License Application (“BLA”) for cosibelimab for the treatment of patients with metastatic cutaneous squamous cell carcinoma (“cSCC”) or locally advanced cSCC who are not candidates for curative surgery or radiation, 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, projections of publication and regulatory submission timelines, and our planned price disruptive strategy generating substantial market share for cosibelimab in the U.S. Factors that could cause our actual results to differ materially include the following: the risk that FDA will not accept the BLA submission; 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; 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 for the fiscal year ended December 31, 2021, 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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Source: Checkpoint Therapeutics, Inc