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Checkpoint Therapeutics to Present Cosibelimab Interim Results from Registration-Enabling Trial at ESMO Virtual Congress 2020

- *Presentation to highlight updated interim data from global trial in patients with metastatic cutaneous squamous cell carcinoma*
- *Over 50% of enrollment target achieved; full enrollment expected around year-end*
- *Potential for cosibelimab to be a best-in-class product with market disruptive pricing in a $25 billion PD-(L)1 class*

NEW YORK, July 27, 2020 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that an abstract highlighting updated interim safety and efficacy data from the ongoing registration-enabling clinical trial of cosibelimab in patients with metastatic cutaneous squamous cell carcinoma ("mCSCC") has been accepted for e-poster presentation at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020, to be held September 19-21, 2020.

Cosibelimab is a potential best-in-class, high affinity, fully-human IgG1 monoclonal antibody 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 to reactivate an antitumor immune response. Cosibelimab is currently being studied in a global, open-label, registration-enabling Phase 1 clinical trial intended to support U.S., EU and other foreign marketing approval applications worldwide. Enrollment in the mCSCC trial has surpassed 50% of the enrollment target, with completion of enrollment expected around year-end and full top-line results anticipated next year. Checkpoint is also enrolling patients with locally advanced cutaneous squamous cell carcinoma to support a potential second indication for cosibelimab.

James F. Oliviero, President and CEO of Checkpoint stated, "We believe cosibelimab is a best-in-class anti-PD-L1 antibody, which we plan to commercialize at a substantially lower price in comparison to currently marketed anti-PD-(L)1 therapies. Through our market disruptive pricing strategy, we believe cosibelimab will obtain meaningful and rapid market share in the $25 billion PD-(L)1 class, while significantly lowering the barrier of high out-of-pocket costs patients endure worldwide to access premium-priced cancer therapies." Mr. Oliviero continued, "We are excited to present updated interim data from our pivotal mCSCC

trial at the upcoming ESMO Congress, as we continue to make significant progress towards completing enrollment around year-end. We recently enhanced our enrollment efforts through the opening of clinical sites in two additional countries and intend to open sites in other western European countries this quarter to further accelerate enrollment in mCSCC and additional potential indications for cosibelimab."

Previously released interim results for cosibelimab were presented in a poster presentation at the ESMO Congress 2019. Results included a 50% objective response rate by investigator assessment in the first 14 mCSCC patients, including one complete response. All responses (100%) were confirmed and ongoing at the time of analysis. A copy of the ESMO Congress 2019 poster presentation is available on the Publications page of the Pipeline section of Checkpoint's website, www.checkpointtx.com.

In January 2020, Checkpoint announced that the U.S. Food and Drug Administration had confirmed the registration submission pathway for cosibelimab in mCSCC based on the ongoing clinical trial, which has a target enrollment of approximately 75 patients and a primary efficacy endpoint of confirmed objective response rate assessed by independent central review.

About Cutaneous Squamous Cell Carcinoma
Cutaneous squamous cell carcinoma ("CSCC") is the second most common human cancer in the United States, with an estimated annual incidence of 700,000 cases. While most cases are localized tumors amenable to curative resection, approximately 8% of patients will experience a local recurrence, 5% of patients will develop nodal metastases, and an estimated 2% of patients will die from their disease. Ten-year survival rates are less than 20% for patients with regional lymph-node involvement. For those patients who develop distant metastases, the median survival time is estimated to be less than two years. 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 (formerly referred to as CK-301) 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. PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, and is utilized by tumor cells as an immune escape mechanism. 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 global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, 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 New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release may contain "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. Such statements include, but are not limited to, any statements relating to our plans to submit one or more applications for marketing approval for cosibelimab, statements regarding the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, statements relating to the functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. 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.

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