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Checkpoint Therapeutics Announces Completion of Enrollment in the Registration-Enabling Trial of Cosibelimab in Metastatic Cutaneous Squamous Cell Carcinoma

- *Top-line results expected in 4Q 2021*
- *Targeting BLA submission in 1H 2022*
- *Market-disruptive pricing planned in $25 billion and growing PD-(L)1 market*

NEW YORK, May 12, 2021 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced the completion of enrollment for the metastatic cutaneous squamous cell carcinoma ("cSCC") cohort in its registration-enabling clinical trial of anti-PD-L1 antibody, cosibelimab.

In January 2020, Checkpoint announced that the U.S. Food and Drug Administration had confirmed the registration submission pathway for cosibelimab in metastatic cSCC 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. Top-line results are expected in the fourth quarter of 2021 and, upon a successful outcome, Checkpoint intends to submit a Biologics License Application ("BLA") for cosibelimab in the first half of 2022, followed shortly thereafter by a Marketing Authorization Application submission in Europe. Additionally, Checkpoint continues to enroll a registration-enabling cohort of patients with locally advanced cSCC and anticipates that this second indication will also be included in the planned BLA and MAA submissions next year.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, "We are pleased to report the completion of enrollment for our metastatic cSCC cohort, with over 75 patients enrolled, which we expect will enable a readout of top-line results in the fourth quarter of this year." Mr. Oliviero continued, "Based on the interim data presented last year at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020 and the Society for Immunotherapy of Cancer ("SITC") 35th Anniversary Annual Meeting, we believe cosibelimab has the potential to be a best-in-class anti-PD-L1 antibody, which we intend to commercialize at a substantially lower price in comparison to currently marketed anti-PD-

(L)1 therapies. With a compelling safety and efficacy profile, as well as our market disruptive pricing strategy, we believe cosibelimab can achieve meaningful and rapid market share in the $25 billion and growing PD-(L)1 class."

About 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. 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 half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of top-line results, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy, product development programs and commercial prospects, 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 and commercial prospects; 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 Securities and Exchange Commission 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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