January 13, 2020

Checkpoint Therapeutics Announces Confirmation of Registration Path for Cosibelimab in Metastatic Cutaneous Squamous Cell Carcinoma

- *FDA feedback supports plan to submit Biologics License Application (BLA) based on data from ongoing Phase 1 trial*
- *One-third enrollment complete in cohort of patients with metastatic cutaneous squamous cell carcinoma*
- *Potential for cosibelimab to be differentiated and lower-cost alternative to available anti-PD-1/L1 mAbs*

NEW YORK, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that feedback from the U.S. Food and Drug Administration ("FDA") has confirmed the company's plan to submit cosibelimab for full approval as a treatment for patients with metastatic cutaneous squamous cell carcinoma ("CSCC") based on efficacy and safety data from the ongoing open-label, multicenter, Phase 1 clinical trial, Study CK-301-101 (NCT03212404). This registration-enabling clinical trial is currently enrolling a cohort of patients with metastatic CSCC, with a target enrollment of approximately 75 to 100 patients and a primary efficacy endpoint of confirmed objective response rate ("ORR") assessed by independent central review.

"We are pleased to have reached consensus with the FDA on the overall development program to support a BLA submission for cosibelimab in metastatic CSCC," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "With approximately one-third of target patient enrollment in the metastatic CSCC cohort now reached, we anticipate completing enrollment by year-end and, subject to meeting the trial's endpoints, submitting a BLA for cosibelimab in 2021. We look forward to positioning cosibelimab as a differentiated and lower-cost alternative to the approved therapy currently available for this indication."

Positive interim results for cosibelimab were presented at the European Society for Medical Oncology ("ESMO") Congress 2019 in Barcelona, Spain. The poster presentation provided interim efficacy and safety results from the ongoing clinical trial, including a 50% ORR by investigator assessment in the first 14 evaluable patients in the metastatic CSCC cohort. One patient achieved a complete response and six patients achieved partial responses. All

seven responses (100%) were confirmed and ongoing at the time of analysis. Additionally, cosibelimab appeared to be safe and well-tolerated in 81 treated patients with diverse tumor types. A copy of the ESMO Congress poster presentation is available on the Publications page of the Pipeline section of Checkpoint's website, www.checkpointtx.com.

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 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 with a half-life that supports sustained >99% target tumor occupancy 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 potentially differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application submissions. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor ("EGFR") inhibitor, in a Phase 1 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer ("NSCLC"). 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 BLAs and seek approvals 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 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.

Company Contacts:
Jaclyn Jaffe and William Begien
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:
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

Source: Checkpoint Therapeutics, Inc