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Checkpoint Therapeutics Announces Presentation of Updated Cosibelimab Lung Cancer Results at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting

- *44.0% objective response rate and 10.3-month median progression-free survival observed in non-small cell lung cancer (NSCLC) cohort*
- *Phase 3 registration-enabling trial planned in first-line metastatic NSCLC*

NEW YORK, Nov. 09, 2020 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced updated interim results from the ongoing global, open-label, multicohort Phase 1 clinical trial of its anti-PD-L1 antibody, cosibelimab, in patients with advanced cancers, including a cohort of patients with previously untreated high PD-L1 expressing advanced non-small cell lung cancer ("NSCLC"). The updated interim results are being presented in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting being held virtually from November 9-14, 2020.

"The single-agent activity of cosibelimab in NSCLC is compelling, with the observed 44.0% objective response rate and 10.3-month median progression-free survival comparing favorably to the datasets generated in similar subjects from the PD-(L)1 therapies available today. Based on the strength of these results, we intend to initiate a Phase 3 registration-enabling trial evaluating cosibelimab in combination with chemotherapy in first-line, metastatic NSCLC patients," said James F. Oliviero, President and Chief Executive Officer of Checkpoint. "The annual market for PD-(L)1 therapies in NSCLC is approximately $10 billion and growing. If approved, we believe cosibelimab could capture meaningful market share as a lower-priced alternative to therapies currently available, and NSCLC is an ideal follow-on to our planned first indication of cutaneous squamous cell carcinoma, for which top-line results from an on-going registration-enabling trial are expected in the second half of 2021."

Summary of NSCLC Data Presented at SITC:
The ongoing trial is evaluating cosibelimab administered as a fixed dose of 800 mg every two weeks or 1200 mg every three weeks. The NSCLC cohort includes patients with Stage IV NSCLC with high (tumor proportion score ≥50%) PD-L1 tumor expression as determined

by immunohistochemistry, with no prior systemic treatment for advanced/metastatic NSCLC and no epidermal growth factor receptor ("EGFR") activating mutation or anaplastic lymphoma kinase ("ALK") translocation.

As of the interim analysis, 25 patients with NSCLC were enrolled and evaluable for efficacy by investigator assessment with at least one post-baseline tumor assessment or discontinued treatment prior. Tumor response assessments are summarized in the table below.

Tumor Response by RECIST 1.1	**NSCLC (n=25)**
Best overall response, n (%)	
Complete response	-
Partial response	11 (44.0)
Stable disease	8 (32.0)
Progressive disease	2 (8.0)
Not evaluated/done[1]	4 (16.0)
Objective response rate, % (95% CI)	**44.0 (24.4, 65.1)**
Response ongoing, n (%)	4 (36.4)
Median duration of response, months (min, max)	15.3 (5.7, 20.5+)
Median progression-free survival, months (95% confidence interval)	10.3 (7.0, 13.7)

Objective response rate = best overall response of complete response or partial response divided by the number of evaluable patients. [1]Represents patients who discontinued study without a post-baseline tumor assessment.

At the time of analysis, 123 patients with advanced cancers had been treated with cosibelimab and were evaluable for safety. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to anti-PD-1 therapies currently available. The most common treatment-related adverse events ("TRAEs") included fatigue (n=19, 15.4%) and rash (n=17, 13.8%), with only 2 patients (1.6%) discontinuing treatment due to a TRAE. Grade ≥3 TRAEs occurred in only 6 patients (4.9%), most commonly anemia and fatigue (each n=2, 1.6%, grade 3 only).

A copy of the poster presentation is available on the Publications page of the Pipeline section of Checkpoint's website, www.checkpointtx.com.

Additional information on the meeting can be found on the SITC website,www.sitcancer.org.

About Lung Cancer

According to the American Cancer Society, it is estimated that more than 228,000 Americans will be diagnosed with lung cancer in 2020, and non-small cell lung cancer accounts for 80-85% of all lung cancers. It is estimated that approximately 85% of lung cancer diagnoses in the United States are made when the disease is in the advanced stages.

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 Biologics License Applications 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 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, 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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