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Checkpoint Therapeutics Announces Initiation of CONTERNO Phase 3 Trial of Cosibelimab Combined with Chemotherapy in Patients with First-Line Non-Squamous Non-Small Cell Lung Cancer

WALTHAM, Mass., Dec. 08, 2021 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced the initiation of the CONTERNO study, a global, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-squamous non-small cell lung cancer (NSCLC). The primary endpoint for the CONTERNO Phase 3 trial is overall survival (OS), and the study is designed to support full regulatory approvals worldwide.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, “We are excited to develop this combination in NSCLC, with the goal of extending the lives of patients with lung cancer and providing expanded access and fewer obstacles to potentially life-saving immunotherapy treatment.” Mr. Oliviero continued, “Our strategy since our founding has been to enter the largest markets in this class with a focus on highly competitive pricing, and there is no more impactful indication to execute on this approach than NSCLC with approximately 1.7 million new worldwide cases reported in 2020.”

About the CONTERNO Study
The CONTERNO study (ClinicalTrials.gov, NCT04786964) is a Phase 3, open-label, multi-center, randomized trial investigating cosibelimab (1200mg every three weeks) combined with pemetrexed and investigator’s choice of platinum chemotherapy (either carboplatin or cisplatin) versus pemetrexed and platinum chemotherapy alone in patients with previously untreated stage IV non-squamous NSCLC and with no EGFR mutations or ALK translocations. The primary endpoint is OS. Key secondary endpoints include progression-free survival, objective response rate and safety. Approximately 560 subjects will be randomized in a 2:1 ratio to receive cosibelimab in combination with chemotherapy or chemotherapy alone.

About Non-Small Cell Lung Cancer
Lung cancer is the most common cancer worldwide according to the World Health Organization, accounting for more than 2 million new cases diagnosed each year. Non-small cell lung cancer (NSCLC) accounts for approximately 85% of lung cancer diagnoses, resulting in approximately 1.7 million new cases each year.Currently, the five-year survival

rate for lung cancer is less than 20%, decreasing further when the disease is diagnosed at later stages. The majority of people with NSCLC are diagnosed with advanced or Stage III or IV disease. Lung cancer is by far the leading cause of cancer death among both men and women, making up almost 25% of all cancer deaths.

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 Waltham, MA 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 cosibelimab's potential to act synergistically with chemotherapy to improve patient survival, the stated primary and secondary endpoints may not achieve statistical significance, delays in the enrollment of patients in this trial may delay or prevent our plans to seek approvals for cosibelimab in this indication, 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 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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