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Checkpoint Therapeutics Announces Positive Topline Results from the Registration-Enabling Trial of Cosibelimab in Metastatic Cutaneous Squamous Cell Carcinoma

- *Study met primary endpoint with 47.4% objective response rate*
- *Safety and tolerability profile consistent with previously reported data*
- *Planned BLA submission on track for later this year*
- *Conference call to be held today, Tuesday, January 25, 2022, at 8:30 AM ET*

WALTHAM, Mass., Jan. 25, 2022 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced positive topline results from its registration-enabling clinical trial evaluating the safety and efficacy of its anti-PD-L1 antibody, cosibelimab, administered as a fixed dose of 800 mg every two weeks in patients with metastatic cutaneous squamous cell carcinoma (“cSCC”).

The study met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate (“ORR”) of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 (“RECIST 1.1”) criteria. The median duration of response (“DOR”) had not yet been reached at the data cut-off point (76% of responses are ongoing). Safety data across 201 patients with advanced cancers enrolled and treated in all cohorts of the ongoing study remain consistent with those previously reported, with the majority of treatment-emergent adverse events reported as Grade 1 or 2 in severity. Based on these results, Checkpoint intends to submit a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration for cosibelimab later this year, to be followed by a marketing authorization application (“MAA”) submission in Europe and additional potential submissions in markets worldwide.

“Most people don’t realize that cutaneous squamous cell carcinoma is the second most common form of skin cancer. While treatable with surgery when caught early, cSCC patients diagnosed with advanced disease that has recurred or metastasized have traditionally faced a poor prognosis and often suffer from painful physical discomfort,” commented Professor Philip Clingan, Medical Oncologist at Southern Medical Day Care Centre in Australia and co-principal investigator of the trial. “These impressive results demonstrate that cosibelimab, a novel PD-L1 antibody with a unique two-fold mechanism of action, has the potential to offer physicians a new treatment option that provides compelling efficacy, complemented by a favorable tolerability profile, for patients living with this devastating disease.”

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, “We are thrilled to report these topline results from our pivotal trial of cosibelimab in metastatic cutaneous squamous cell carcinoma. We believe the strong ORR result is attributable to cosibelimab’s differentiated, two-fold mechanism of action of engaging both T-cells and natural killer cells, while also demonstrating a potential favorable safety profile through its binding to PD-L1, reported in literature as associated with lower rates of severe or worse adverse events as compared to PD-1 therapy. We extend our sincere thanks to the patients, caregivers, investigators and their site staff for their dedication to this trial, particularly during these challenging times globally. We look forward to a detailed presentation of the data at an upcoming medical meeting.”

Mr. Oliviero continued, “Upon approval, we intend to position cosibelimab at a lower price point than currently available PD-(L)1 therapies, which we hope will lead to meaningful market share in the U.S. and international markets around the world. We also believe the safety and efficacy profile of cosibelimab could make cosibelimab an attractive agent for use in combination regimens, potentially with drug candidates within our current portfolio, additional molecules we may in-license, and synergistic molecules through potential collaborations, particularly those that can take advantage of the two-fold mechanism of action of cosibelimab.”

Additionally, Checkpoint continues to enroll a registration-enabling cohort of patients with locally advanced cSCC, anticipating this potential second indication could be included in the planned initial BLA submission, as well as the global, randomized Phase 3 (CONTERNO) 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.

Conference Call Information
Checkpoint will host a conference call today, Tuesday, January 25, 2022, at 8:30 AM ET to discuss the topline results. In order to participate in the conference call, please dial 1-877-269-7756 (U.S.), 1-201-689-7817 (outside of the U.S.).

A live webcast of this conference call will be available on the IR Calendar page under News & Events, located within the Investors section of Checkpoint’s website, https://ir.checkpointtx.com/event-calendar/default.aspx, and an audio recording of the conference call will also be available for replay for a period of approximately 30 days following the call.

About Cutaneous Squamous Cell Carcinoma
Cutaneous squamous cell carcinoma (cSCC) is the second most common type of skin cancer in the United States, with an estimated annual incidence of approximately 1 million cases according to the Skin Cancer Foundation. While most cases are localized tumors amenable to curative resection, approximately 40,000 cases will become advanced and an estimated 15,000 people will die from their disease. 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 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 contains “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, that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, the two-fold mechanism of action of cosibelimab translating into potential enhanced efficacy, and projections of publication and regulatory submission timelines. Factors that could cause our actual results to differ materially include the following: our ability to successfully deliver the complete dataset from the clinical trial and complete a BLA submission on schedule as planned; the risk that topline data remains subject to audit and verification procedures that may result in the final data being materially different from the topline data we previously published; the risk that safety issues or trends will be observed in the clinical trial when the full safety dataset is available and analyzed; the risk that a positive primary endpoint does not translate to all, or any, secondary endpoints being met; risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the Phase 1 clinical trial; the risk that the clinical results from the Phase 1 clinical trial will not support regulatory approval of cosibelimab to treat cSCC or, if approved, that cosibelimab will not be commercially successful; risks related to our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks related to our need for substantial additional funds; other uncertainties inherent in research and development; our dependence on third-party suppliers; government regulation; patent and

intellectual property matters; competition; and our ability to achieve the milestones we project, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and in our other filings with the U.S. Securities and Exchange Commission. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

Any forward-looking statements set forth in this press release speak only as of the date of this press release. 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. This press release and prior releases are available at www.checkpointtx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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