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Checkpoint Therapeutics Announces Presentation of New Cosibelimab Pharmacokinetic Data Supporting Extended-Interval Dosing

Results support comparability of cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens

Biologics License Application for cosibelimab under review by U.S. FDA; PDUFA goal date of January 3, 2024

WALTHAM, Mass., June 28, 2023 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that new pharmacokinetic ("PK") modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented today at the Population Approach Group Europe ("PAGE") 2023 annual meeting, taking place in A Coruña, Spain.

The poster presentation, entitled "Population Pharmacokinetic Analysis of PD-L1 Checkpoint Inhibitor Cosibelimab in Subjects with Advanced Cancers," compares cosibelimab exposures from over 200 patients enrolled in the multicenter, multiregional pivotal trial of cosibelimab in which cohorts of patients were dosed at either 800 mg every two weeks ("Q2W") or 1200 mg every three weeks ("Q3W"). The patient exposure results provide evidence that cosibelimab dosed at 800 mg Q2W and 1200 mg Q3W intervals are comparable based on the PK-related criteria outlined in U.S. Food and Drug Administration ("FDA") guidance for supporting alternative dosing regimens for PD-L1 antibodies. These data support the proposed 1200 mg Q3W commercial dosing regimen for cosibelimab included in the Biologics License Application ("BLA") for advanced cutaneous squamous cell carcinoma currently under review by the FDA with a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024.

These most recent results build on the previous presentation of PK and target occupancy data showing that cosibelimab doses of 800 mg Q2W and 1200 mg Q3W are both expected to achieve over 99% PD-L1 target occupancy throughout the respective dosing intervals to restore T-cell function in order to induce an anti-tumor response.

"We are firmly committed to improving all aspects of cancer care, including a focus on

providing greater flexibility and convenience in administering cosibelimab upon its potential U.S. marketing approval in early January as a treatment for advanced cutaneous squamous cell carcinoma," said James Oliviero, President and Chief Executive Officer of Checkpoint. Mr. Oliviero continued, "These data further support the comparability of the two-week and three-week dosing regimens for cosibelimab and are included in the BLA submission currently under FDA review. If approved, based on its unique mechanism of action and compelling efficacy and safety profile, we believe cosibelimab has the potential to capture significant market share as a differentiated and possibly best-in-class treatment for patients with cutaneous squamous cell carcinoma, which we estimate to be a $1.6 billion U.S. market opportunity."

A copy of the poster presentation is availablehere.

Additional information on the meeting can be found on the PAGE website,www.page-meeting.org.

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 open-label, multi-regional, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including cohorts in metastatic and locally advanced cutaneous squamous cell carcinoma ("cSCC") intended to support one or more applications for marketing approval. Based on positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint submitted a Biologics License Application ("BLA") for these indications in January 2023, which application is filed and under review with a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, olafertinib (formerly 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 regarding the FDA review of the BLA for the approval of cosibelimab for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation and the commercial potential of cosibelimab if the BLA is approved, statements related to the comparability of the Q2W and Q3W dosing regimens, 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 our projections of publication and regulatory review timelines.

Factors that could cause our actual results to differ materially include the following: the risk that topline and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline or interim 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 chemistry, manufacturing and controls and contract manufacturing relationships; 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; unfavorable market or other economic conditions; and our ability to achieve the milestones we project, including the risk that the evolving and unpredictable Russia/Ukraine conflict and COVID-19 pandemic delay achievement of those milestones. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K, 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.

Company Contact:
Jaclyn Jaffe
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:
Katie Kennedy
Gregory FCA
(610) 731-1045

checkpoint@gregoryfca.com

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