May 13, 2022

Checkpoint Therapeutics Receives Pediatric Investigational Plan Waivers for Cosibelimab from the European Medicines Agency and U.K. Medicines & Healthcare Products Regulatory Agency

Waivers remove requirement to conduct pediatric clinical studies to support cosibelimab marketing authorization applications in Europe

WALTHAM, Mass., May 13, 2022 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (Checkpoint) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that it has received Pediatric Investigation Plan (PIP) product-specific waivers from the European Medicines Agency (EMA) and the U.K. Medicines & Healthcare products Regulatory Agency (MHRA) for cosibelimab in cutaneous squamous cell carcinoma (cSCC). Following the announcement of positive topline data from Checkpoint's registration-enabling clinical trial in January 2022, a U.S. Biologics License Application (BLA) submission for cosibelimab is planned for later this year, to be followed by marketing authorization applications (MAAs) in Europe.

The regulatory processes for the registration of new medicines with the EMA and MHRA require pharmaceutical companies to provide a PIP outlining their strategy for investigating the new medicine in a pediatric population. In some instances, a waiver may be granted by the respective regulatory authority when the development of a medicine for use in children is not feasible or appropriate, as is the case for cosibelimab in cSCC.

"These waivers from the EMA and MHRA are important milestones in the European regulatory process for cosibelimab in cSCC," said James Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "Such PIP waivers enable us to proceed more quickly and cost-effectively when advancing our marketing approval applications with the EMA and MHRA, avoiding the significant time and expense required to conduct a pediatric clinical study in Europe. As such, these PIP waivers enhance the value of the cosibelimab program in Europe for Checkpoint and potential partners."

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 ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma (cSCC) intended to support one or more applications for marketing approval. Following positive topline results in metastatic cSCC, Checkpoint intends to submit a Biologics License Application for this indication later this year. Additionally, 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 is ongoing. 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 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 BLA and MAA submissions 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 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 for the fiscal year ended December 31, 2021 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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Source: Checkpoint Therapeutics, Inc