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Checkpoint Therapeutics Announces Presentation of Anti-PD-L1 Cosibelimab Data at the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting

NEW YORK, Nov. 08, 2019 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (Checkpoint) (NASDAQ: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced that new pharmacokinetic and target occupancy modeling data for cosibelimab (formerly referred to as CK-301) are being presented today at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting, taking place in National Harbor, MD.

The poster, entitled, “Semi-mechanistic PK and target-occupancy modeling to support dose justification for anti-PD-L1 clinical candidate CK-301 (TG-1501) in oncology patients,” compares pharmacokinetic and tumor target occupancy data at steady state under various dosing regimens of cosibelimab to those of three marketed anti-PD-L1 monoclonal antibodies, atezolizumab, durvalumab and avelumab. The results demonstrate that cosibelimab dosed at 800 mg and 1200 mg once every two weeks or every three weeks is expected to achieve over 99% PD-L1 target occupancy throughout the dosing interval, which is comparable to atezolizumab and durvalumab, and higher than avelumab, at their approved doses. These data support the potential of cosibelimab’s once every two-week and every three-week dosing regimens to achieve and maintain the PD-L1 target occupancy required to restore T-cell function and an anti-tumor response.

These data follow the presentation of positive interim clinical results for cosibelimab at the European Society for Medical Oncology (ESMO) Congress 2019 in September. Checkpoint is currently enrolling cutaneous squamous cell carcinoma patients in an expanded cohort of its ongoing Phase 1 clinical trial to support an initial Biologics License Application submission for cosibelimab. Additional monotherapy and combination Phase 3 clinical trials are planned to expand the potential market opportunity for cosibelimab to multiple non-small cell lung cancer indications.

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 Cosibelimab

Cosibelimab (formerly referred to as CK-301) is a 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. PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, and is utilized by tumor cells as an immune escape mechanism. 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 with a half-life that supports sustained >99% target tumor occupancy 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 potentially differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application submissions. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation epidermal growth factor receptor (EGFR) inhibitor, in a Phase 1 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer (NSCLC). 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 BLAs and seek accelerated or full 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 how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, 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 relating to our growth strategy; 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 SEC 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.

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