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Checkpoint Therapeutics Initiates Registrational Development Programs for Anti-PD-L1 Antibody CK-301

Ongoing endometrial and colorectal cancer cohorts intended to support BLA submissions

NEW YORK, Jan. 07, 2019 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ: CKPT), a clinical-stage immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced that the ongoing multi-center clinical trial of CK-301 has been expanded to enroll patients in three cohorts intended to support requests for accelerated approval and Biologics License Application (BLA) submissions to the U.S. Food and Drug Administration (FDA). These cohorts include:

- Microsatellite instability-high (MSI-H) endometrial cancer that has progressed following one or two prior anti-cancer therapies;
- Microsatellite stable (MSS) endometrial cancer that has progressed following one or two prior anti-cancer therapies; and
- MSI-H or mismatch repair deficient (dMMR) colorectal cancer that has progressed on or after, or been intolerant of, previous treatments, including a fluoropyrimidine- and oxaliplatin- and irinotecan-based chemotherapy.

Each cohort is evaluating a fixed dose of 800 mg CK-301 every two weeks (Q2W). The primary endpoint for each cohort is objective response rate (ORR), and secondary endpoints include duration of response (DOR), progression-free survival (PFS), and overall survival (OS). The ongoing trial is also enrolling cohorts of patients with non-small cell lung cancer (NSCLC) and cutaneous squamous cell carcinoma.

"We are excited to advance our first immuno-oncology drug candidate, CK-301, into these potentially registration-enabling cohorts, representing a significant milestone in the execution of our strategy to obtain multiple accelerated approvals for our anti-PD-L1 antibody," said James F. Oliviero, President and Chief Executive Officer of Checkpoint. "We look forward to presenting interim safety and efficacy data from the ongoing clinical trial in the coming months."

The Phase 1, open-label, multi-center trial is evaluating the safety and tolerability of ascending doses of CK-301 in checkpoint therapy-naïve patients with selected recurrent or

metastatic cancers. Following completion of dose escalation in 2018, multiple dose expansion cohorts were initiated. Preliminary data from the ongoing trial suggest that CK-301 is safe and well-tolerated across dose levels ranging from 200 mg to 800 mg administered every two weeks and 1200 mg administered every three weeks, with treatment-related adverse events consistent with marketed anti-PD-1/PD-L1 antibodies.

About CK-301

CK-301 is a 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. CK-301'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.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation EGFR inhibitor, in a Phase 1/2 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer (NSCLC). In addition, Checkpoint is currently evaluating its lead antibody product candidate, CK-301, an 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. Checkpoint is headquartered in New York City. 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, statements relating to our plans to submit one or more BLAs and seek accelerated approvals for CK-301, 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; risks relating to our ability to seek accelerated approvals for our drug candidates; 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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