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Checkpoint Therapeutics Announces Positive Interim Clinical Results of Anti-PD-L1 Antibody Cosibelimab

>40% objective response rates observed in first-line non-small cell lung cancer and cutaneous squamous cell carcinoma

Well-tolerated safety profile

Enrollment ongoing in expansion cohorts intended to support potential BLA submissions

NEW YORK, May 01, 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 positive interim results from its ongoing multicenter Phase 1 clinical trial of cosibelimab (formerly referred to as CK-301). Cosibelimab is a high affinity, fully-human IgG1 monoclonal antibody 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 is potentially differentiated from currently marketed PD-1 and PD-L1 antibodies with a half-life that supports sustained >99% tumor target 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.

"We are excited by the compelling efficacy demonstrated in the interim data of cosibelimab, with greater than 40% objective response rates in non-small cell lung cancer and cutaneous squamous cell carcinoma, as well as the strikingly high rate of patients with target lesion reductions across diverse tumor types," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "The goal of this study was to demonstrate that cosibelimab has a safety and efficacy profile consistent with marketed PD-(L)1 inhibitors, so we are thrilled to report these strong results for our potentially differentiated anti-PD-L1 antibody." Mr. Oliviero added, "While the approved PD-(L)1 inhibitors have grown into a $20 billion class, there continue to remain areas of unmet medical need and underserved patient populations in the U.S. and around the world that lack access to such treatments. We look forward to continuing to enroll patients into potential registration-enabling cohorts in order to support one or more marketing application submissions based on this ongoing clinical trial."

Summary of Interim Clinical Results

The Phase 1, open-label, multicenter trial (NCT03212404) is evaluating the safety, efficacy and pharmacokinetics of ascending doses of cosibelimab in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Following completion of dose escalation in 2018, multiple disease-specific expansion cohorts were initiated evaluating a fixed dose of 800 mg cosibelimab dosed intravenously every two weeks (Q2W).

As of April 23, 2019, 65 patients with diverse tumor types were treated with cosibelimab at 20 clinical sites located in Australia, New Zealand, Thailand, Poland and Russia. At the time of data cutoff, 42 patients remain on cosibelimab treatment (range: 1-17+ months). Cosibelimab appeared to be safe and well-tolerated with no dose-limiting toxicities. Treatment-related adverse events ("AEs") occurred in 32/65 (49%) patients, most commonly rash (n=9, 14%) and fatigue (n=6, 9%). Treatment-related grade ≥3 AEs occurred in 5/65 (8%) patients, all grade 3, and included anemia, asthenia, hypertension, hyponatremia, and high blood pressure (n=1 [2%] each).

Thirty-six patients had at least one post-baseline tumor response assessment and were evaluable for efficacy (17 additional patients are pending first post-baseline response assessment). Key efficacy results were as follows:

Responses by Tumor Type	Objective Response Rate (RECIST v1.1) % (n)	Patients with Reductions in Sum of Target Lesions % (n)	Disease Control Rate (RECIST v1.1) % (n)
All Tumor Types Combined	28% (10/36)	67% (24/36)	75% (27/36)
NSCLC (1st Line with High [≥50%] PD-L1)	42% (5/12)	75% (9/12)	83% (10/12)
Cutaneous Squamous Cell Carcinoma	43% (3/7)	71% (5/7)	86% (6/7)
Melanoma	14% (1/7)	57% (4/7)	71% (5/7)
Other: Colorectal, Head/Neck Sq Cell, Hodgkin's Lymphoma, Mesothelioma, NSCLC (2nd Line), Urothelial	10% (1/10)	60% (6/10)	60% (6/10)

Objective response rate = best overall response of complete response or partial response divided by the number of evaluable patients; Disease control rate = best overall response of complete response, partial response, or stable disease divided by the number of evaluable patients; NSCLC = non-small cell lung cancer; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors guideline, version 1.1.

Median duration of response was not reached. Data will continue to mature with additional follow-up and will be submitted for presentation at an upcoming medical meeting.

Enrollment Ongoing in Potential Registration-Enabling Expansion Cohorts

Checkpoint continues 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. 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.

The ongoing trial is also enrolling a cohort of patients with cutaneous squamous cell carcinoma that, if successful, could support full approval for cosibelimab in this indication.

Each cohort is evaluating a fixed dose of 800 mg cosibelimab dosed intravenously every two weeks. The primary endpoint for each cohort is objective response rate, and secondary endpoints include duration of response, progression-free survival, and overall survival.

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 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. In addition, Checkpoint is currently evaluating its lead antibody product candidate, cosibelimab, 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 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, statements relating to our plans to submit one or more BLAs and seek accelerated approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, 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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