September 30, 2019

Checkpoint Therapeutics Announces Presentation of Positive Interim Clinical Results for Anti-PD-L1 Cosibelimab at the European Society for Medical Oncology (ESMO) Congress 2019

- *50% objective response rate observed in cutaneous squamous cell carcinoma (CSCC)*
- *40% objective response rate observed in non-small cell lung cancer*
- *Well-tolerated safety profile across all cohorts*
- *Enrollment ongoing to support initial Biologics License Application submission in CSCC*
- *Potential to be differentiated and lower-cost alternative to available anti-PD-1/L1 mAbs*

NEW YORK, Sept. 30, 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 positive interim results for cosibelimab, a potentially differentiated high affinity anti-PD-L1 antibody with functional Fc domain, were presented on Saturday, September 28th, at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain. The poster presentation provided updated interim efficacy and safety results from Checkpoint's ongoing multicenter Phase 1 clinical trial, including expansion cohorts in cutaneous squamous cell carcinoma ("CSCC") and non-small cell lung cancer ("NSCLC"). Checkpoint continues to enroll CSCC patients to support an initial Biologics License Application ("BLA") submission for cosibelimab based on this ongoing clinical trial.

"The compelling data presented at the ESMO Congress demonstrate strong and durable efficacy in CSCC and NSCLC and a potentially favorable safety profile as compared to the class of anti-PD-1 antibodies currently available," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "As the second deadliest skin cancer after melanoma, it is estimated that CSCC is responsible for approximately 7,000 deaths each year in the United States. We are confident that cosibelimab could soon provide CSCC patients with a highly effective and better tolerated treatment option as compared to the single anti-PD-1 therapy on the market today. With 25 CSCC patients enrolled to date, we intend to fully enroll the CSCC cohort in 2020 to potentially support an initial BLA filing, with the goal of positioning cosibelimab as a differentiated and lower-cost alternative to the approved therapy available today."

Summary of Interim Clinical Results

The Phase 1, open-label, multicenter trial (NCT03212404) is evaluating the safety, efficacy and pharmacokinetics of cosibelimab in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Following dose escalation, the trial initiated multiple disease-specific expansion cohorts, including in CSCC and NSCLC, evaluating a fixed dose of 800 mg cosibelimab dosed intravenously every two weeks. As of August 5, 2019, 81 patients with diverse tumor types have been treated with cosibelimab.

Sixty-eight patients were evaluable for efficacy at the time of data cutoff, having at least two tumor assessments or discontinued treatment prior. Key efficacy results were as follows:

- 50% objective response rate ("ORR") in CSCC patients per RECIST v1.1. One patient achieved a complete response and six patients achieved partial responses. All seven responses (100%) are confirmed and ongoing with the longest duration at 11.4 months at the time of analysis.

- 40% ORR in first-line NSCLC patients with high (≥50%) expression of PD-L1 per RECIST v1.1. Ten patients achieved partial responses (eight confirmed and two pending confirmation). Nine of 10 responses (90%) are ongoing with the longest duration at 11 months at the time of analysis.

The best overall tumor response is shown below for all tumor types and the subgroup cohorts of CSCC and NSCLC.

Best Overall Tumor Response by RECIST v1.1	**All Tumor Types (n=68)**	**CSCC (n=14)**	**NSCLC (n=25)**
Complete response, n (%)	1 (1.5)	1 (7.1)	0 (0.0)
Partial response, n (%)	18 (26.4)	6 (42.9)	10 (40.0)
Stable disease, n (%)	20 (29.4)	2 (14.3)	9 (36.0)
Progressive disease, n (%)	14 (20.6)	2 (14.3)	2 (8.0)
Not evaluated/done, n (%)	15 (22.1)	3 (21.4)	4 (16.0)
Overall response rate, % (95% CI)	**27.9 (17.7, 40.1)**	**50.0 (23.0, 77.0)**	**40.0 (21.1, 61.3)**
Response ongoing, n (%)	17/19 (89.5)	7/7 (100.0)	9/10 (90.0)
Median duration of response, months (min, max)	Not reached (0.1, 11.4)	Not reached (2.5, 11.4)	Not reached (0.1, 11.0)
Disease control rate, %	57.3	64.2	76.0

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.

Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies. Treatment-related adverse events ("AEs") occurred in 48/81 (59%) patients, most commonly rash (n=11, 13.6%), fatigue (n=8, 9.9%), hypothyroidism (n=7, 8.6%), anemia (n=6, 7.4%), alanine aminotransferase increase, diarrhea, and infusion-related reaction (n=5, 6.2% each). Treatment-related grade ≥3 AEs occurred in 5/81 (6%) patients, with only two patients (2.5%) discontinuing treatment due to a treatment-related AE.

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 ESMO website,www.esmo.org.

About Cutaneous Squamous Cell Carcinoma
Cutaneous squamous cell carcinoma ("CSCC") is the second most common human cancer in the United States, with an estimated annual incidence of 700,000 cases. While most cases are localized tumors amenable to curative resection, approximately 8% of patients will experience a local recurrence, 5% of patients will develop nodal metastases, and an estimated 2% of patients will die from their disease. Ten-year survival rates are less than 20% for patients with regional lymph-node involvement. For those patients who develop distant metastases, the median survival time is estimated to be less than two years. 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 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 epidermal growth factor receptor ("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, 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. 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 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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