

Madrid, Spain, 3 November, 2020 – [Pivotal](#) announced today that it has been contracted by [Checkpoint Therapeutics Inc.](#)

, a New York City-based biotechnology company, to provide expert clinical research services in Europe for its upcoming clinical study of its Programmed Death-Ligand 1 (PD-L1) inhibitor, cosibelimab (CK-301), in cutaneous squamous cell carcinoma (cSCC) patients.

Cosibelimab is a potential, best-in-class, high affinity, fully-human IgG1 monoclonal antibody that directly binds to PD-L1 and blocks the PD-L1 interaction with the programmed death receptor-1 (PD-1) and B7.1 receptors to reactivate an antitumor immune response. In addition, cosibelimab has a functional Fc region that may bind and activate natural killer (NK) cells to enable cell-mediated antibody-dependent cellular cytotoxicity (ADCC).

Cosibelimab is currently being studied in a global, open-label, registration-enabling Phase 1 clinical trial intended to support U.S., EU and other foreign marketing approval applications worldwide. Enrollment in the metastatic cSCC cohort of the trial has already surpassed 60% of the enrollment target. Checkpoint is also enrolling patients with locally advanced cSCC to support a potential second indication for cosibelimab.

“Previously released interim results for cosibelimab were presented in a poster presentation at the ESMO Virtual Congress 2020. Results included a 51.4% objective response rate by investigator assessment in the first 37 metastatic cSCC patients, including several complete responses. Safety and tolerability among the first 114 patients treated with all histologies was excellent with grade ≥ 3 treatment-related toxicity of only 5%,” said James Oliviero, CEO, Checkpoint Therapeutics. “We are proud to partner with Pivotal to gain access to Western European countries to accelerate the completion of enrollment of this pivotal study in cSCC and to help support a planned MAA submission for European approval based on data from the ongoing study, as well as access to KOLs in key European countries.”

About 2.2 million people worldwide have cSCC at any given time. It makes up about 20% of all skin cancer cases. Most squamous cell carcinomas of the skin are surgically treated with a free margin of healthy tissue and this is the preferred treatment modality if possible. Radiotherapy, given as external beam radiotherapy or as brachytherapy (internal radiotherapy), can also be used as complementary treatment, after a recurrence or in places where aesthetics sequela are unacceptable. 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.

“The combined expertise in clinical research excellence of both Checkpoint Therapeutics and Pivotal will enable us to accelerate research and provide access to a novel therapy in this unmet medical need area,” said Dr Lourdes Huarte, VP Regulatory & Clinical Operations at Pivotal. “We look forward to positively impacting the lives of people facing cSCC and its complications in Europe.”

About Pivotal

Pivotal was founded in 2001 by Dr. Ibrahim Farr on the principle that strategic medical advice and support should be the backbone of all clinical trials. After working for over two decades in the pharmaceutical industry, Dr. Farr recognized the need for a medium-sized CRO with a solid internal medical franchise that could act not only as the "doers" but also as the "co-thinkers" for their clients, through its strategic scientific advice. To date, we are the trusted advisor and counselor for many companies to deliver maximum value in their drug development programs. We are a leading privately-held European CRO and, since inception, we have experienced a fast and steady organic growth and we are currently employing some 200 cross-functional professionals.

Pivotal clients' portfolio spans major pharmaceutical, biotechnological, medical device and nutrition companies, and we have long-standing relations with over 188 clients. Pivotal has extensive experience across major therapeutic areas and phases I to IV. Our highly customized teams bring to each client a combination of broad industry knowledge and operational excellence, to offer our clients fresh perspectives and breakthrough business insights. Additionally, we have built a strong oncology, innovative therapies, rare diseases and early phases hub that enables us to tackle our customers most difficult challenges, turning recommendations into concrete actions. By remaining true to our core principles and values, our vision is to become our client's preferred outsourcing solution partner.

For more information, please visit www.pivotal.es

About Checkpoint Therapeutics, Inc.

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 intended to support one or more applications for marketing approval. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, 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 New York City and was founded by Fortress Biotech, Inc.

Écrit par Pivotal

Lundi, 09 Novembre 2020 12:24 - Mis à jour Lundi, 09 Novembre 2020 12:57

For more information, please 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 Checkpoint Therapeutics’ plans to submit one or more Biologics License Applications (BLAs) and seek regulatory approvals for cosibelimab worldwide, statements regarding the potential differentiation of cosibelimab, statements relating to the functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to the timing of the completion of enrollment and full top-line results, 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 that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to Checkpoint Therapeutics’ growth strategy; its 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; Checkpoint Therapeutics’ dependence on third-party suppliers; its ability to attract, integrate and retain key personnel; the early stage of products under development; Checkpoint Therapeutics’ need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in Checkpoint Therapeutics’ Securities and Exchange Commission filings. Checkpoint Therapeutics expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and it claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.