



Checkpoint Therapeutics Initiates Dose Expansion Portion of Phase 1 Trial of Anti-PD-L1 Antibody CK-301

CK-301 was safe and well tolerated in dose escalation portion of Phase 1 trial

New York, NY – March 21, 2018 – 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 the completion of the dose escalation portion of the ongoing Phase 1 clinical trial of CK-301, a fully human anti-PD-L1 antibody, in selected recurrent or metastatic cancers, and the initiation of the first dose expansion cohort, which is evaluating an 800 mg dose of CK-301 administered every two weeks.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “The completion of the dose escalation portion of our Phase 1 trial marks an important milestone in the clinical development of our anti-PD-L1 antibody, CK-301. Our focus now shifts to generating efficacy data in the dose expansion portion of the trial through the enrollment of patients with tumor types believed to have a high potential for objective response to anti-PD-L1 monotherapy. We look forward to reporting initial data from this expansion cohort in the second half of 2018, and are targeting the initiation of our first registration trial in first-line non-small cell lung cancer in the first quarter of 2019.”

Preliminary data from the dose escalation portion of the Phase 1 trial suggest that CK-301 is safe and well tolerated across three fixed dose levels ranging from 200 mg to 800 mg administered every two weeks. Treatment-related adverse events were mild to moderate and consistent with other approved PD-L1 antibodies. No dose-limiting toxicities have been reported and no patients have discontinued therapy to date.

Based on these data, Checkpoint has commenced its first dose expansion cohort evaluating the fixed dose of 800 mg, the highest dose tested in dose escalation, every two weeks in up to 40 checkpoint therapy-naïve patients with select tumor types associated with high clinical response rates to anti-PD-1/L1 monotherapies, with a priority on enrolling first-line non-small cell lung cancer patients whose tumors have high PD-L1 expression.

Additional information on the trial can be found on www.clinicaltrials.gov using the identifier NCT03212404.

About the Phase 1 CK-301 Trial

The Phase 1, first-in-human, open-label, multicenter trial is evaluating the safety and tolerability of ascending doses of CK-301 in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Secondary endpoints include the evaluation or characterization of the pharmacokinetics, immunogenicity and preliminary efficacy of CK-301. Following dose escalation, up to four dose expansion cohorts may be enrolled to further characterize the safety and efficacy of CK-301 in specific patient

subgroups. The trial is currently enrolling patients at sites across Australia, New Zealand and Thailand.

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 currently evaluating its lead product candidate CK-301, a fully human anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in a Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Checkpoint plans to develop CK-301 as a treatment for patients with non-small cell lung cancer (“NSCLC”) and other solid tumors. In addition, Checkpoint is evaluating its small-molecule, targeted anti-cancer agent, CK-101, in the Phase 1 portion of a Phase 1/2 clinical trial for the treatment of patients with epidermal growth factor receptor (“EGFR”) mutation-positive NSCLC. Checkpoint’s pipeline also includes antibodies that target glucocorticoid-induced TNFR-related protein (“GITR”) and carbonic anhydrase IX (“CAIX”), in addition to oral, small-molecule, targeted anti-cancer agents that inhibit bromodomain and extra-terminal (“BET”) proteins and poly (ADP-ribose) polymerase (“PARP”). Checkpoint is a majority-controlled subsidiary of Fortress Biotech, Inc., and is headquartered in New York City. For more information, visit www.checkpointtx.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) (NASDAQ: FBIO) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.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 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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