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Checkpoint Therapeutics Initiates Phase 1 Study of Anti-PD-L1 Antibody CK-301

NEW YORK, Oct. 05, 2017 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ:CKPT), a Fortress Biotech (NASDAQ:FBIO) company, today announced that the first patient has been dosed in a Phase 1 clinical study evaluating the safety and tolerability of CK-301 in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers.

CK-301 is a fully human monoclonal antibody that binds to Programmed Death-Ligand 1 ("PD-L1") and blocks its interaction with the Programmed Death-1 ("PD-1") and B7.1 receptors. This has the potential to lead to the recovery of an anti-tumor immune response and the immune-mediated eradication of tumors.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, stated, "We are proud to announce that our first immuno-oncology asset has entered the clinic, and look forward to assessing its potential as a therapeutic option in many oncological indications, both as a monotherapy and in combination with other targeted therapies and anti-tumor, immune-response potentiating compounds."

Mr. Oliviero continued, "The targeting of PD-L1 to block the PD-1/PD-L1 pathway has become well-validated in cancer immunotherapy, which may significantly reduce the clinical development timeline for CK-301. By enrolling only checkpoint therapy-naïve patients, we expect to see signals of efficacy in both the dose escalation and expansion portions of the study, potentially enabling our first registration study by the end of next year. We look forward to providing clinical updates on the study in the first half of 2018."

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

About the Phase 1 CK-301 Study

The first-in-human, Phase 1, open-label, multicenter study 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 study will initially enroll patients in study sites across Australia and New Zealand.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. Checkpoint's broad pipeline consists of fully human, immuno-oncology and checkpoint inhibitor antibodies licensed from the Dana-Farber Cancer Institute that target programmed death-ligand 1 ("PD-L1"); glucocorticoid-induced TNFR-related protein ("GITR"); and carbonic anhydrase IX ("CAIX"). In addition, Checkpoint is developing three oral, small-molecule, targeted anti-cancer agents that inhibit epidermal growth-factor receptor ("EGFR") mutations, the bromodomain and extra-terminal ("BET") protein BRD4, and poly (ADP-ribose) polymerase ("PARP"). Checkpoint will also seek to expand its pipeline to create additional proprietary combination therapies that leverage the immune system and complementary mechanisms. 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") 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 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 licensings, 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. 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 price. Factors that could cause actual results to differ materially from those currently anticipated are: the risk that Checkpoint will not be able to advance its research programs; risks related to the timing of starting and completing of clinical trials; risks inherent in research and development activities; risks related to its growth strategy; its ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; its dependence on third-party suppliers; its ability to attract, integrate, and retain key personnel; the early stage of products under development; its need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in Checkpoint's public filings and reports. Checkpoint 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 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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