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Checkpoint Therapeutics Initiates Phase 1/2 Study of CK-101 – A Novel Third-Generation EGFR Inhibitor

NEW YORK, Oct. 03, 2016 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint"), a Fortress Biotech (NASDAQ:FBIO) company, today announced that the first patient has been dosed in a Phase 1/2 clinical study of CK-101, its novel, oral, third-generation epidermal growth factor receptor ("EGFR") inhibitor product candidate.

The Phase 1 dose escalation portion of the study will evaluate the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and/or recommended Phase 2 dose of CK-101. The Phase 2 portion of the study is planned to evaluate the safety and efficacy of the recommended Phase 2 dose of CK-101 in patients with EGFR T790M mutation-positive non-small cell lung cancer.

"This is a very exciting time for Checkpoint, with the initiation of our first clinical program for a product candidate in our portfolio," said James F. Oliviero, III, President and CEO of Checkpoint Therapeutics. "We believe there is a need for additional treatment options for non-small cell lung cancer patients with the EGFR T790M mutation. We look forward to moving the CK-101 clinical program forward, with the goal of developing CK-101 both as a monotherapy and in combination with our portfolio of immuno-oncology agents."

Checkpoint holds an exclusive worldwide license (except with respect to certain Asian countries) to CK-101 (also known as RX518), which it acquired from NeuPharma, Inc. in 2015.

About the CK-101-101 Study

Study CK-101-101 is a first-in-human, two-part, open-label, safety, pharmacokinetic, and efficacy study of CK-101 administered daily as a single-agent in ascending doses in patients with advanced solid tumor cancer, followed by a Phase 2 portion at the recommended Phase 2 dose in previously treated non-small cell lung cancer patients who have documented evidence of the EGFR T790M mutation and have failed treatment with a first-line EGFR inhibitor. The Phase 2 portion of the study is expected to enroll approximately 60 patients, and the primary endpoint is objective response rate.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint"), a Fortress Biotech company, is an innovative, 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 aims to acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, Checkpoint is developing a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute ("Dana-Farber"). The portfolio of antibodies Checkpoint licensed from Dana-Farber includes antibodies targeting Programmed death-ligand 1 ("PD-L1"), Glucocorticoid-induced TNFR related protein ("GITR") and carbonic anhydrase IX ("CAIX"). Checkpoint plans to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as data suggests that combinations of these targets may work synergistically together. Checkpoint has also licensed and is developing three oral, small molecule, targeted anti-cancer agents, consisting of an inhibitor of epidermal growth factor receptor ("EGFR") mutations, an inhibitor of the bromodomain and extra-terminal ("BET") protein, BRD4, and an inhibitor of poly (ADP-ribose) polymerase ("PARP"). Checkpoint will also seek to add additional immuno-oncology drugs and other targeted therapies in order to create wholly-owned proprietary combinations that leverage the immune system and complimentary mechanisms. Checkpoint 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 plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress will leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, Fortress will provide funding and management services to each of the Fortress Companies and, from time to time, Fortress and the Fortress Companies will seek licensing, 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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