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Checkpoint Therapeutics Announces Clinical Data on EGFR Inhibitor CK-101 Selected for Late-Breaking Oral Presentation at IASLC 19th World Conference on Lung Cancer

NEW YORK, Aug. 13, 2018 (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 preliminary safety and efficacy data from a Phase 1/2 clinical trial of CK-101 (also known as RX518), a third-generation epidermal growth factor receptor ("EGFR") tyrosine kinase inhibitor ("TKI") being evaluated in advanced non-small cell lung cancer, has been selected for a late-breaking oral presentation at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer, to be held September 23-26, 2018, in Toronto.

"We are thrilled to announce that preliminary data from the Phase 1/2 trial of our novel third-generation EGFR inhibitor has been selected for a late-breaking oral presentation at the World Conference on Lung Cancer. This marks the first clinical data to be reported by Checkpoint, an important clinical and corporate milestone," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "Third-generation EGFR inhibitors are highly selective and have the potential to demonstrate improved safety and tolerability versus earlier-generation therapies. There is currently only one third-generation EGFR inhibitor approved and we believe CK-101 could be second to market potentially with a differentiated safety profile."

Details of the presentation are as follows:

Title: CK-101 (RX518), a Third Generation Mutant-Selective Inhibitor of EGFR in NSCLC: Results of an Ongoing Phase I/II Trial

Date: Monday, Sept. 24, 2018

Session: Novel Therapies in ROS1, HER2 and EGFR

Presenter: Melissa L. Johnson, M.D., Associate Director, Lung Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, PLLC, Nashville, Tenn.

The full abstract will be posted on the conference website on Wednesday, Sept. 5, 2018, at 5 p.m. ET. For additional information, please visit: <https://wcl2018.iaslc.org/#>.

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

About CK-101

CK-101 (also known as RX518) is an oral, third-generation, irreversible kinase inhibitor against selective mutations in the EGFR gene. Activating mutations in the tyrosine kinase domain of EGFR, such as L858R and exon 19 deletion, are found in approximately 20 percent of patients with advanced non-small cell lung cancer (“NSCLC”).

Compared to chemotherapy, first-generation EGFR inhibitors significantly improved objective response rate and progression-free survival in previously untreated NSCLC patients carrying EGFR mutations. However, tumor progression could develop due to resistance mutations, often within months of treatment with first-generation EGFR inhibitors. The EGFR T790M “gatekeeper” mutation is the most common resistance mutation found in patients treated with first-generation EGFR inhibitors. The mutation decreases the affinity of first-generation inhibitors to EGFR kinase domain, rendering the drugs ineffective. Second-generation EGFR inhibitors have improved potency against the T790M mutation, but have not provided meaningful benefits in NSCLC patients due to toxicity from also inhibiting wild-type EGFR. Third-generation EGFR inhibitors are designed to be highly selective against both EGFR-TKI-sensitizing and resistance mutations, with minimal activity on wild-type EGFR, thereby improving tolerability and safety profiles.

Checkpoint Therapeutics is developing CK-101 for the treatment of NSCLC patients carrying the susceptible EGFR mutations. These include the EGFR T790M mutation in second-line NSCLC patients, as well as the EGFR L858R and exon 19 deletion mutations in first-line NSCLC patients.

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, 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, CK-301, an 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 NSCLC and other solid tumors. 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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