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Checkpoint Therapeutics Announces Presentation of Updated Data from Phase 1/2 Trial of EGFR Inhibitor CK-101

Data were featured in an oral presentation at the IASLC 19th World Conference on Lung Cancer

Phase 3 trial in treatment-naïve EGFR mutation-positive NSCLC patients targeted to commence in 2019

NEW YORK, Sept. 25, 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 positive preliminary safety and efficacy data from an ongoing Phase 1/2 clinical trial of CK-101 were presented yesterday in an oral presentation at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer in Toronto. The oral presentation included further details on, and updates from, the dataset announced previously. CK-101 is a third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) being evaluated in advanced non-small cell lung cancer (NSCLC).

"The oral presentation included exciting updates to the data released in the abstract, including intracranial disease responses to treatment with CK-101 in patients with brain metastases present at baseline indicating that CK-101 may cross the blood-brain barrier to reach metastases in the central nervous system, as well as an additional partial response post-data cutoff in a T790M mutation-positive NSCLC patient that failed previous TKI therapy," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "Based on these data, we believe CK-101 has the potential to be an effective and differentiated treatment option in a potential $6 billion market currently dominated by one approved therapy."

Highlights from the Oral Presentation

- CK-101 was well-tolerated across multiple dose groups
  - Most adverse events were Grade 1-2
  - Maximum-tolerated dose was not defined; no reported dose-limiting toxicities or treatment-related serious adverse events
  - No events of interstitial lung disease, pneumonitis, QTc prolongation,

cardiomyopathy, nail toxicities, stomatitis or hyperglycemia, which are notable observed side effects of marketed TKI therapies

- CK-101 demonstrates preliminary activity in EGFR mutation-positive NSCLC
  - 75% (6 of 8) objective response rate (ORR) in treatment-naïve patients
  - 100% (19 of 19) disease control rate (DCR), including 84% (16 of 19) of patients with target lesion reductions versus baseline
  - 60% (3 of 5) of patients with baseline brain metastases had intracranial disease response

- Enrollment in the trial is ongoing to identify the optimal dose to maximize therapeutic effect, following which a Phase 3 trial is planned to initiate in 2019 in treatment-naïve EGFR mutation-positive NSCLC patients.

The first-in-human, multicenter trial is evaluating CK-101 in NSCLC patients with EGFR mutations and other advanced malignancies (NCT02926768). Following dose escalation ranging from 100 mg to 1,200 mg/day in patients with any solid tumor where targeted EGFR was deemed reasonable, a first dose-expansion cohort was enrolled at 400 mg twice daily in patients with a confirmed diagnosis of either (1) EGFR mutation-positive advanced or metastatic NSCLC without prior exposure to EGFR-TKI therapy, or (2) T790M-positive advanced or metastatic NSCLC with disease progression on previous EGFR-TKI therapy. There was no limit on the number of prior lines of systemic therapy patients received prior to entering the trial.

A copy of the oral presentation slides is available on the Publications page in the Pipeline section of Checkpoint's website, www.checkpointtx.com.

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.

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 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, a Fortress Biotech company, 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 identify doses of CK-101 that increase drug exposure at safe levels and optimize efficacy; our ability to commence a Phase 3 trial for CK-101 in 2019; 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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