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Checkpoint Therapeutics Reports Preclinical Data for Two Oncology Programs

Data supports clinical development of EGFR inhibitor and anti-PD-L1 antibody

NEW YORK, April 04, 2017 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (OTCQX:CKPT), a Fortress Biotech (NASDAQ:FBIO) company, today announced that preclinical data on its third-generation epidermal growth factor receptor ("EGFR") inhibitor, CK-101, and anti-programmed cell death ligand-1 ("PD-L1") antibody, CK-301, were presented this week in poster sessions at the American Association for Cancer Research (AACR) Annual Meeting. The data presented strongly support the clinical development of these therapies.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "These encouraging preclinical data demonstrate the potential of our EGFR inhibitor and anti-PD-L1 checkpoint antibody to be effective new treatment options for patients suffering from cancer. We look forward to advancing these drug candidates through the stages of clinical development, both as monotherapies as well as in combination with each other."

Key conclusions from the posters are as follows:

[CK-101 \(RX518\), a Mutant-Selective Inhibitor of EGFR that Overcomes T790M-Mediated Resistance in Non-Small Cell Lung Cancer \(NSCLC\)](#)

CK-101 (also known as RX518) is a novel, irreversible, orally administered EGFR kinase inhibitor that specifically targets the mutant forms of EGFR, including T790M, while exhibiting minimal activity toward the wild-type EGFR. Cell proliferation assays in human cancer cell lines in vitro, and xenograft studies conducted in mouse models of NSCLC demonstrated:

- CK-101 is a potent, mutant-selective inhibitor of both the activating (exon 19 deletion) and resistance mutations (L858R / T790M double mutation).
- CK-101 inhibited tumor growth as a single agent in a NSCLC model with a single activating mutation (exon 19 deletion).
- CK-101 showed dose-dependent inhibition of tumor growth as a single agent in a L858R / T790M double mutant NSCLC model.

- CK-101 has little inhibitory potency toward wild-type EGFR (i.e., CK-101 was more than 100-fold less potent against wild-type EGFR than against L858R / T790M double mutation).

These data supported the initiation of a Phase 1/2 clinical trial in September 2016 (ClinicalTrials.gov: [NCT02926768](https://clinicaltrials.gov/ct2/show/study/NCT02926768)). The Phase 1 dose-escalation portion is ongoing, and Checkpoint expects to initiate the Phase 2 portion in patients with EGFR T790M mutation-positive NSCLC cancer in the second half of 2017.

Preclinical Characterization of a Novel Fully Human IgG1 Anti-PD-L1 mAb CK-301

Based on the various assays performed, the poster concluded:

- CK-301 is a high affinity PD-L1 specific fully humanized IgG1 antibody which blocks binding of PD-L1 to PD-1.
- Activity of CK-301 in all assays tested was similar to anti-PD-L1's used as active controls (surrogates of avelumab, atezolizumab or durvalumab).
- Similar to the approved anti-PD-L1, avelumab, CK-301 has the potential to induce ADCC (antibody-dependent cell-mediated cytotoxicity).

A first-in-human Phase 1 study of CK-301 is planned to commence this year.

The posters are available on the Publications page within the Pipeline section of Checkpoint's website, www.checkpointtx.com.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint"), a Fortress Biotech company, 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 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 develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ:NHLD), a diversified independent brokerage company (together with its subsidiaries, "NHLD"). 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.

Contacts:

Jaclyn Jaffe
Checkpoint Therapeutics, Inc.
781-652-4500; ir@checkpointtx.com

Fortress Biotech Media Relations
Laura Bagby
6 Degrees
(312) 448-8098; lbagby@6degreespr.com



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