

September 11, 2017



## **Checkpoint Therapeutics Receives Orphan Drug Designation for CK-101 for the Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer**

NEW YORK, Sept. 11, 2017 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ:CKPT), a Fortress Biotech (NASDAQ:FBIO) company, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to CK-101 (also known as RX518), the Company's third-generation epidermal growth-factor receptor (EGFR) inhibitor, for the treatment of EGFR mutation-positive non-small cell lung cancer (NSCLC).

CK-101 is currently being studied in the Phase 1 dose-escalation portion of a Phase 1/2 clinical study. The Phase 1 portion of the study is evaluating 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 dose for the Phase 2 portion of the study. The Phase 2 portion will evaluate the safety and efficacy of CK-101 in patients with EGFR T790M mutation-positive NSCLC.

"Securing Orphan Drug Designation is a significant milestone that will support the clinical development of our lead targeted therapy, CK-101, in EGFR mutation-positive NSCLC," said James F. Oliviero, President and Chief Executive Officer of Checkpoint. "This Orphan Drug Designation builds upon the issued U.S. composition of matter patent for CK-101, and could provide the benefit of additional market exclusivity."

Orphan Drug Designation is granted by the FDA to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases / disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain incentives that may include tax credits toward the cost of clinical trials and prescription drug user fee waivers. If a product holding Orphan Drug Designation receives the first FDA approval for the disease in which it has such designation, the product is entitled to seven years of market exclusivity, which is independent from intellectual property protection.

### **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 headquartered in New York City. For more information, visit [www.checkpointtx.com](http://www.checkpointtx.com).

Checkpoint is a majority-controlled subsidiary of Fortress Biotech, Inc.

### **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](http://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 anticipation of benefits from Orphan Drug Designation for CK-101, 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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Source: Checkpoint Therapeutics, Inc