

December 22, 2014

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# **Can-Fite Doses First Patient in Global Phase II Liver Cancer Trial for CF102**

**Trial follows successful Phase I/II study which met all study endpoints**

**CF102 granted Orphan Drug Status for this indication by the FDA**

**Global Industry Analysts predict that the global market for liver cancer is projected to exceed \$2B by 2015**

PETACH TIKVA, Israel, Dec. 22, 2014 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer and inflammatory diseases, today announced that it has dosed the first patient in a Phase II trial for the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

The Phase II randomized, double-blind, placebo controlled trial is to be conducted in the U.S., Europe and Israel with an estimated 78 patients to be enrolled. [CF 102](#) is being evaluated for efficacy and safety as a second-line treatment for advanced HCC in subjects with Child-Pugh B who failed Nexavar as a first line treatment. The first patient was dosed at the study's Israeli site, the Rabin Medical Center. The primary endpoint of the study is overall patient survival.

This Phase II study follows favorable results in Can-Fite's Phase I/II study, which was an open-label, dose-escalation study that evaluated the safety, tolerability, pharmacokinetics, and pharmacodynamics of the orally administered CF102 in patients with advanced primary HCC. Data from that trial showed prolonged survival, stable disease in some patients, and regression of skin tumor metastases, as well as a favorable safety profile and lack of hepatotoxicity.

"We believe we have reached an important milestone in this trial by commencing the dosing of patients with CF102. We are proud to be working with some of the top medical institutions in the world on this trial, including Tufts Medical School in the U.S. and the Rabin Medical Center in Israel. As we continue to screen for new patients, we look forward to advancing the trial towards full enrollment," stated Can-Fite CEO Dr. Pnina Fishman.

"If the Phase II data show results similar to our Phase I/II study, we believe this would indicate that CF102 may offer clear benefits and a prolonged life for liver cancer patients," Dr. Fishman added.

The U.S. Food and Drug Administration has granted Orphan Drug Status to Can-Fite's CF 102 for this indication. Israel's Ministry of Health has also approved CF102 for Compassionate Use in liver cancer. Global Industry Analysts predicts that the global market for liver cancer is projected to exceed \$2B by 2015.

## About CF102

CF102 is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). A3AR is highly expressed in tumor cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug. In Can-Fite's pre-clinical and clinical studies, CF102 has demonstrated a robust anti-tumor effect via deregulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells. CF102 is in Phase II clinical trials for the treatment of liver cancer in the U.S., Israel, and Europe. The U.S. Food and Drug Administration has agreed with Can-Fite's Phase II study protocol and had previously granted Can-Fite Orphan Drug Designation for CF102 in the treatment of hepatocellular carcinoma, the most common form of liver cancer.

## About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI) is an advanced clinical stage drug development company with a platform technology that is designed to address multi-billion dollar markets in the treatment of cancer and inflammatory diseases. The Company's CF101 is in Phase II/III trials for the treatment of psoriasis and the Company is preparing for a Phase III CF101 trial for rheumatoid arthritis. Can-Fite's liver cancer drug CF102 is commencing Phase II trials and has been granted Orphan Drug Designation by the U.S. Food and Drug Administration. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. These drugs have an excellent safety profile with experience in over 1,200 patients in clinical studies to date. For more information, please visit: [www.can-fite.com](http://www.can-fite.com)

## Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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