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Can-Fite: Phase II Study Protocol to Treat Patients with Advanced Liver Cancer with CF102 has been Approved by the IRB in Israel

CF102 has Orphan Drug Designation from U.S. FDA

Global Liver Cancer Drug Market is Expected to Exceed \$2 Billion by 2015

PETACH TIKVA, Israel, March 17, 2014 /PRNewswire/ --**Can-Fite BioPharma (TASE: CFBI), (NYSE MKT:CANF)**, a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, announced today that a Phase II study protocol for the treatment of advanced liver cancer with its CF102 has been approved by the Institutional Review Board (IRB) in Israel.

The company plans to conduct the Phase II study in Israel, Europe and the US and it will include 78 subjects that will be dosed with the drug as a second-line treatment of advanced hepatocellular carcinoma with Child-Pugh Class B cirrhosis. The study will investigate the efficacy and safety of CF102 vs. placebo. The protocol has been approved by the IRB at the Rabin Medical Center, Petach Tikva, and the company intends to follow up with European and US submissions shortly. The study protocol was developed with the assistance of Dr. Keith Stuart, MD, Chairman, Department of Hematology and Oncology Professor of Medicine, Tufts University School of Medicine, a well-known internationally expert in Liver Cancer. This center will also participate in the study.

The US Food and Drug Administration (FDA) has granted Orphan Drug designation for CF102, for the treatment of hepatocellular carcinoma. FDA orphan drug status grants various incentives for developing these drugs, including shortened approval procedures, tax breaks on R&D costs, and financing assistance. If the drug is the first to reach market, it also receives seven years exclusivity.

According to [Global Industry Analysts](#), the global liver cancer drug market is expected to exceed \$2 billion by 2015.

The company reported earlier that data from the Phase I/II study were [published](#) recently in [The Oncologist](#), one of the leading journals in this field, and was presented at the 18th World Congress on Advances in Oncology. The company reported that the Phase I/II study data demonstrated that the trial objectives were successfully achieved, demonstrating a very favorable safety profile for CF102 in a patient population with hepatocellular carcinoma and Child-Pugh cirrhosis classes A and B. In addition, the median overall survival time was very encouraging given that most patients were treated in the second-line setting and some were Child-Pugh Class B. Another finding indicated that the A3 adenosine receptor, which is the

target of CF102, can serve as a biomarker to predict the patients' reaction to treatment with CF102. Interestingly, one of the patients included in the Phase I/II study has been treated for 4 years with CF102 and is continuing to be treated, with CF102.

About CF102

CF102 is a small orally bioavailable drug which binds with high affinity and selectivity to the A3 adenosine receptor. The latter 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 our pre-clinical and clinical studies, CF102 induces a robust anti-tumor effect via de-regulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd is an Israeli public company, the ordinary shares of which are traded on the Tel Aviv Stock Exchange (the "TASE") (TASE: CFBI). Level II American Depository Receipts of the Company currently trade on the NYSE MKT (NYSE MKT: CANF). Can-Fite, which commenced business activity in 2000, was founded by Pnina Fishman, Ph.D., researcher in the Rabin Medical Center, and Ilan Cohn Ph.D., patent attorney and senior partner at Reinhold Cohn Patent Attorneys in Israel. Dr. Fishman serves as the Chief Executive Officer of Can-Fite. Dr. Fishman founded Can-Fite on the basis of her scientific findings, and Can-Fite is focused on the development of small molecule orally bioavailable drugs, in particular, ligands that bind to the A3 adenosine receptor. Such drugs mediate anti-inflammatory and anti-cancer effects and the A3AR is developed as a biological predictive marker. Can-Fite's lead drug candidate, CF101, is in clinical development for the treatment of autoimmune inflammatory diseases including Rheumatoid Arthritis and Psoriasis. Can-Fite's CF102 drug candidate is being developed for the treatment of liver diseases and CF602 is being developed for the treatment of inflammation and sexual dysfunction. To date, more than 1000 patients have participated in clinical trials conducted by Can-Fite. Can-Fite previously spun off its activity in the ophthalmic field to OphthaliX Inc., in which it holds 82%, and is currently listed on the U.S. Over-the-Counter Markets (OTCQB: OPLI).

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