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# Can-Fite Submitted Phase II Study Protocol with CF102 to Treat Patients with Advanced Liver Cancer

**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, Feb. 6, 2014 /PRNewswire/ -- **Can-Fite BioPharma (TASE: CFBI), (OTC: CANFY)**, 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 drug candidate has been submitted.

The company plans to conduct the Phase II study in Israel, Europe and the US and will include 78 subjects (less than what has been reported previously since the company is treating a patient population with a more advanced disease) with 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 submitted to the ethics committee in Israel 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.

The US Food and Drug Administration (FDA) has granted Orphan Drug designation for CF102, for the treatment of hepatocellular carcinoma.

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 was [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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### **Forward-Looking Statements**

This press release contains 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 (the "SEC"), 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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