



## **Can-Fite to Initiate a Phase II Study with CF102 in 130 Patients with Advanced Liver Cancer**

**Petach Tikva, Israel, August 27, 2013: 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 it will initiate a Phase 2 study with its anti-cancer drug CF102, the second drug in its pipeline of A3 adenosine receptor ligands. The company is studying CF102 as a treatment for liver cancer (hepatocellular carcinoma, or HCC). Based on the successful conclusion of a former Phase 1/2 trial, the company developed a Phase 2 protocol that will be conducted under an open IND with the FDA. The study will include 130 patients with an advanced liver cancer disease and CF102 will be given as a standalone drug.

The data of the Phase 1/2 study were published lately in *The Oncologist*, one of the leading journals in this field and will be presented in the 18th World Congress on Advances in Oncology. The company reported that the Phase 1/2 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 that has been included in the Phase 1/2 study is treated for 4 years with CF102 and is doing very well.

Global liver cancer drugs' market is expected to exceed \$2 billion by 2015.<sup>1</sup>

### **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. 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 (TASE: CFBI). American Depository Receipts of the company are traded on the over-the-counter market (OTC: CANFY). The company, 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. Pnina Fishman serves as CEO of the company. The company was founded on the basis of

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<sup>1</sup> Form 8-K for ONYX PHARMACEUTICALS INC 24,4,2011

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Fishman's scientific findings, and is focused on the development of small molecule orally bioavailable drugs, ligands to the A3 adenosine receptor. The latter mediates anti-inflammatory and anti-cancer effects and is suggested as a biological predictive marker. The company's lead drug, CF101, is in clinical development for the treatment of autoimmune inflammatory diseases. The CF102 drug candidate is being developed for the treatment of liver diseases. Can-Fite has a wealth of clinical experience: to date, more than 700 patients have participated in clinical trials conducted by the company. Can-Fite previously licensed its activity in the ophthalmic field to OphthaliX Inc., in which it holds a controlling interest (OTC: OPLI).

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### Safe Harbor Statement

Any statements in this press release that relate to the Company's expectations are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act. The Private Securities Litigation Reform Act of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees. Since this information may involve risks and uncertainties and are subject to change at any time, the Company's actual results may differ materially from expected results. Additional risks associated with Can-Fite's business can be found in its periodic filings with the Tel Aviv Stock Exchange.