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Can-Fite Submits Protocol to U.S. FDA for Phase II Liver Cancer Study

Tufts University will be a clinical site for international trial of CF102 with Orphan Drug Designation

PETACH TIKVA, Israel, April 29, 2014 /PRNewswire/ -- Can-Fite BioPharma Ltd. (NYSE MKT:CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, announced today that it has submitted a study protocol to the U.S. Food and Drug Administration for its Phase II clinical trial of CF102 for the treatment of advanced liver cancer. The FDA has granted Orphan Drug designation to CF102 in this indication. The protocol, which has already been approved by the Institutional Review Board (IRB) in Israel, will also be filed in Europe.

The planned Phase II study will be conducted in Israel, Europe and the U.S. with 78 subjects who will be dosed with CF102 as a second-line treatment of advanced hepatocellular carcinoma (HCC) with Child-Pugh Class B cirrhosis. The study will investigate the efficacy and safety of CF102 as compared to placebo.

Dr. Keith Stuart, MD, assisted in developing the study protocol. He is Chairman, Department of Hematology at Lahey Clinic and Oncology Professor of Medicine, Tufts University School of Medicine. Tufts University will participate as the study's U.S. clinical site.

The protocol submission is supported by strong, positive data from Can-Fite's Phase I/II HCC study published in The Oncologist, and presented at the 18th World Congress on Advances in Oncology. The Phase I/II study data demonstrated that the trial objectives were successfully achieved. CF102 had a very favorable safety profile with very encouraging median overall survival and one patient who has been treated for 4 years with CF102. The A3 adenosine receptor (A3AR), which is the target of CF102, was also found to potentially serve as a biomarker to predict patients' reaction to treatment with CF102.

"We are planning to initiate our Phase II trial for advanced liver cancer during the current quarter. Having already received IRB approval in Israel, we look forward to the FDA's response to the protocol. Advanced liver cancer is an indication that is a clear, unmet medical need and we believe the FDA's Orphan Drug Designation for CF102 will support our clinical development path," stated Can-Fite CEO Dr. Pnina Fishman.

According to Global Industry Analysts, the global liver cancer drug market is expected to exceed $2 billion by 2015.

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. (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 in 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

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 (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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