



Can-Fite Initiates Phase I Multi-Center Trial of CF101 in Combination with Chemotherapy for Various Solid Tumors at Harvard Medical School

**Can-Fite's first US clinical study is now open at Beth Israel Deaconess Medical Center,
Dana-Farber Cancer Institute and Massachusetts General Hospital**

Boston, MA, June 30, 2004 -- Can-Fite Biopharma, Ltd. (www.canfite.com) announced today the opening of its US IND and the initiation of a Phase I study of CF101 in the U.S. in patients with solid tumors. The trial will take place at three Harvard Medical School affiliate hospitals and will investigate combinations of the company's lead drug, CF101, with three different standard chemotherapeutic regimens.

The primary objective of this open-label, dose-escalation Phase I study will be to determine the safety, tolerability and clinical effects of the oral administration of CF101 in combination with one of three different cytotoxic chemotherapy regimens.

CF101 is an A3 adenosine 3-receptor agonist. It modulates down-stream signals controlling cell proliferation. Preclinical studies indicate that the drug has good potential as an anti-cancer drug. These studies also show that CF101 enhances the effect of chemotherapy. In addition, CF101 treatment in animal studies was found to speed up the recovery in white blood cells count following chemotherapy-induced depletion.

"We are pleased to be a part of this exciting research. The pre-clinical data, the company's Phase I data from studies in healthy volunteers and a colorectal cancer study in patients conducted in Israel provide a very strong rationale to study the effect of CF101 in combination with conventional chemotherapy on solid tumors in humans," said Dr. Bruce Dezube, Associate Professor of Medicine in the Harvard Medical School and an oncologist at Beth Israel Deaconess Medical Center (BIDMC), a research affiliate of Harvard Medical School. Prof. Dezube is the principal investigator in this clinical study.

"We are honored to be collaborating with a well-respected institution such as Harvard Medical School and to be working with the outstanding teams at three of America's finest hospitals. This *combination* study in the U.S. will add highly important data on the drug's therapeutic potential. As we are beginning this study, we are nearing the completion of our current Phase II trial in Israel of CF101 as a *monotherapy* for the experimental treatment of colorectal cancer. We are expecting the final results of the latter study in the next few months. This and our U.S. IND are the latest indications that Can-Fite is maintaining momentum and continuing its fast track development," said Dr. Ilan Cohn, CEO of Can-Fite.

About Can-Fite BioPharma, Ltd.

Can-Fite BioPharma Ltd. is a privately held company headquartered in Petach-Tikva, Israel that began operations at the end of 2000. The Company was founded based on the work of Professor Pnina Fishman, formerly a Tumor Immunologist in the Rabin Medical Center in Israel, and who now serves as the Company's Chief Scientific Officer. Professor Fishman addressed a fundamental observation: *why doesn't cancer metastasize in muscle?* She discovered that muscle cells release a molecule with a very potent anti-cancer activity. Her research led to an oral small molecule drug, CF101, which piggybacks on this natural phenomenon and works in a manner similar to that of the natural, muscle-released factor. Today, Can-Fite's research activity is conducted at the Company's laboratories in Petach-Tikvah. The company's U.S. business operations and pre-clinical and clinical development are managed from facilities in the Boston area. Can-Fite is currently engaged in two Phase II trials of its lead drug CF101, one for the treatment of colorectal cancer and the other for rheumatoid arthritis, in addition to research and development of a pipeline of drugs for a variety of clinical indications. The market potential for CF101 is estimated at more than US\$ 1 billion worldwide. Can-Fite is also engaged in a Phase I study of CF101 in combination with chemotherapy to commence in the U.S. in Q2 2004. Dr. Ilan Cohn is the company's President & CEO. Investors in the company include Giza Venture Capital, The Yozma Group, Ascend Technology Ventures, Vitalife, Biocom, BioMedical Innovations Management and BPW Israel Investment LLC.

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