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Press release

Can-Fite: IND submission for Phase I Clinical Trials with its Drug for Liver Diseases CF102

Can-Fite develops CF102 for the treatment of liver cancer, hepatitis virus infections and other liver conditions that represent a current market of about USD 4 billion

Can-Fite estimates that this Phase I study will be initiated in early 2008, subject to FDA approval

Prof. Pnina Fishman, CEO of Can-Fite: "we are making progress according to schedule towards the first clinical trial with CF102. We are pleased to announce that once this trial is underway, Can-Fite will have two pipeline drugs in clinical trials for various indications, including cancer, viral infections and autoimmune inflammatory disease."

Can-Fite BioPharma Ltd., a biotechnology company traded on the Tel Aviv Stock Exchange, is advancing through its development pipeline and prepares for clinical trials with CF102, the second drug candidate in its product pipeline. Can-Fite announced today that it submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) to initiate phase I clinical trials with CF102. Can-Fite's second pipeline drug is intended for the treatment of liver diseases including liver cancer, hepatitis virus infections and liver regeneration. The combined market potential of drugs for these conditions is estimated at about USD 4 billion. Can-Fite estimates that the first clinical trial with CF102 will be initiated in early 2008, subject to FDA approval.

CF102 was developed on the basis of Can-Fite's platform technology and tested in a series of preclinical studies over the past few months. These included Kg drug manufacturing, formulation development, drug packaging, animal toxicology studies, blood clearance rate and metabolism. These trials have shown that the drug is safe and can be tested in human clinical studies. The drug is being developed for three leading indications in liver diseases: liver cancer, hepatitis virus infections and liver regeneration.

Liver cancer affects about 450,000 new patients each year and is highly prevalent in people with hepatitis virus infection or alcohol abuse. This type of cancer is particularly prevalent in Eastern countries due to the high rate of hepatitis virus infections. The current market size of liver cancer is estimated at about USD 0.5 billion due to lack of proper treatment.

Laboratory trials conducted by Can-Fite in collaboration with a leading laboratory at the Temple University, Philadelphia, have shown that CF102 has antiviral activity and is effective against **the hepatitis virus**. The number of people infected with hepatitis B and C virus worldwide is 350 million and 170 million, respectively, and rapidly increasing in the past few years. The hepatitis virus is one of the main causes of

hepatitis. Market size is currently about USD 3 billion per annum due to lack of proper treatment.

Preclinical studies have also shown that CF102 is effective in **liver tissue regeneration** after partial hepatectomy. Partial hepatectomy is usually performed in patients with primary or metastatic liver cancer. Rapid liver regeneration is crucial in these conditions, and regeneration rates determine future liver function and chances for successful recovery. Regeneration of normal liver tissue is also needed to preserve liver function in patients with liver failure. No drugs are currently available to speed up the regeneration process; therefore, developing a drug for the treatment of patients undergoing hepatectomy or patients with liver failure is a top priority. The number of patients requiring liver regeneration is estimated at about 100 million.

Prof. Pnina Fishman, CEO of Can-Fite said today that: "we are making progress according to schedule towards the first clinical trial with CF102. We are pleased to announce that, once this trial is underway, Can-Fite will have two pipeline drugs in clinical trials for various indications, including cancer, viral infections and autoimmune inflammatory disease."

CF101, the other drug being developed by Can-Fite, is in advanced phases of clinical trials. Early this month, Can-Fite announced that CF101 may also be effective for a severe bowel condition called Crohn's disease. Can-Fite also announced that it will continue to develop CF101 for the treatment of rheumatoid arthritis. Can-Fite reported that a phase IIb trial will be initiated in early 2008 as part of the further development of CF101. Phase II clinical trials are also being conducted to test the efficacy of CF101 in the treatment of psoriasis and dry eye syndrome.

CAN-FITE BIOPHARMA LTD is a public company traded on the Tel Aviv Stock Exchange. The Company, which commenced business activity in 2000, was founded by Prof. Pnina Fishman, an investigator from Rabin Medical Center, and patent attorney Dr. Ilan Cohn, a senior associate at Reinhold Cohn Patent Attorneys. Prof. Fishman serves as the CEO of Can-Fite. The Company was founded on the basis of scientific findings made by Prof. Fishman and focuses on the development of molecule-based drugs that bind to receptors of cancerous or inflammatory cells and inhibit their development.

Can-Fite currently has two drugs in development, CF101 and CF102. The company is simultaneously conducting several clinical and preclinical trials with the two drugs for various indications. CF101 is being studied for the treatment of rheumatoid arthritis, dry eye syndrome and psoriasis. Can-Fite has also entered the development of CF102 for the treatment of liver cancer and hepatitis.

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