

October 23, 2007

## **Press release**

## Can-Fite to Conduct a Confirmatory Phase IIb Trial in Early 2008 as Part of Ongoing Development of CF101 for the Treatment of Rheumatoid Arthritis

Can-Fite's Clinical Advisory Board has recommended this advanced trial as further evidence for the efficacy observed in a previous trial; this will give green light to the final phase of development

Prof. Pnina Fishman, CEO of Can-Fite, said that "the confidence expressed by the Clinical Advisory Board (CAB) members in the CF101 drug, the advantages of the drug over currently available medications and its potential as an anti-inflammatory drug, motivates us to proceed vigorously with the development plan for the indication of Rheumatoid Arthritis and for other recently reported indications of CF101 and CF102."

Can-Fite BioPharma Ltd. will conduct in early 2008 a confirmatory Phase IIb trial as part of the ongoing development of CF101 for the treatment of Rheumatoid Arthritis (RA). This is in line with recent recommendations made by Can-Fite's CAB which took place in Boston under the chairmanship of Prof. Weinblatt. The CAB recommendations were endorsed last night by Can-Fite's Board of Directors.

In July, Can-Fite published the results of a Phase IIb study with CF101 in combination with Methotrexate (MTX) indicating that the ACR20 response, which was the primary efficacy end point of the study, showed no difference between the CF101-treated and placebo groups. However, a substantial difference in favor of CF101 was seen in the ACR50, the ACR70 and the EULAR "Good" response measures.

Now, that the CAB has made its recommendations, Can-Fite intends to commence in the first quarter of 2008 an advanced trial similar to the previous one. This trial will include the two dose groups with the best results from the previous trial, in comparison to a control group, and patients will be treated for a period of 12 weeks. The trial will be conducted using a tablet formulation, which was lately developed by the company.

Can-Fite estimates that the trial will be initiated at the first quarter of 2008 and may take about 1 year to complete, including data analysis. Can-Fite will soon file an application with the FDA for this trial, which will be conducted under FDA inspection. If the results are favorable, this would mean that Can-Fite has paved the way towards the final phase of drug development. Can-Fite has sufficient financial resources to complete this trial in parallel to other ongoing clinical studies.

This progress in the development in CF101 was preceded by recent reports on the successful completion of pre-clinical trials in the US with CF102, Can-Fite's second molecule in the pipeline, which is the foundation of a drug for the treatment of several indications in the Hepatology arena, i.e., hepatocellular carcinoma, hepatitis, liver

regeneration. Can-Fite estimates that Phase I clinical trial with CF102 will commence in the coming months.

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**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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