30.04.2009

Press Release

A Phase IIb Study Testing the Combination of Methotrexate and CF101 in Rheumatoid Arthritis Patients Failed to Achieve Primary Efficacy Endpoint

Can-Fite Continues to Develop CF101 as a Stand-alone Therapy for Other Clinical Indications

Can-Fite BioPharma announced today that top line results from its Phase IIb study in rheumatoid arthritis (RA) patients indicate that the study failed to achieve its primary efficacy endpoint.

The Phase IIb RA study enrolled 230 patients in 21 sites in Europe and in Israel. The patients were randomized into 3 groups treated, twice daily, orally, with 0.1 mg or 1 mg of CF101, or placebo. In this study CF101 was given for 12 weeks to patients who were also treated concomitantly with methotrexate.

The primary efficacy endpoint of the study was an ACR20 response. Top level results indicated that there was no statistically significant difference between the groups that received CF101 and the placebo group. Detailed review of the data is ongoing.

CF101 is undergoing two other Phase II clinical studies, one in dry eye (keratoconjunctivitis sicca-KCS) and the other in psoriasis. In distinction from the rheumatoid arthritis study, where CF101 was administered to patients in combination with methotrexate, in the dry eye and the psoriasis studies CF101 is given to patients as monotherapy.

Dr. Pnina Fishman, Can-Fite's CEO, stated that "although the results are disappointing, they are nonetheless a very important milestone in the development of CF101. The lesson to be learned from the Phase IIb RA study is that CF101 will likely not work in combination with methotrexate and the focus should thus be on stand-alone therapeutic uses. In addition to the ongoing Phase II studies in KCS and psoriasis , we have plans to also conduct clinical studies in other indications in which CF101 will be given as a single drug by itself and not in combination. The excellent safety profile and other attributes continue to render CF101 a highly attractive drug candidate."

The company also continues to develop of another drug, CF102. Two Phase I/II studies, one in patients with primary liver cancer (hepatocellular carcinoma) and one in patients with hepatitis C virus infection, are about to begin shortly in Israel.

CAN-FITE BIOPHARMA LTD 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. Pnina Fishman serves as the CEO of Can-Fite. The Company was founded on the basis of scientific findings made by Prof. Pnina 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's development pipeline currently has two drugs: CF101 and CF102. The company is simultaneously conducting several preclinical and clinical trials with the two drugs for various indications. CF101 is being studied for the treatment of dry eye syndrome (Phase II) and psoriasis (Phase II). Can-Fite develops CF102 for the treatment of liver conditions, including liver cancer, hepatitis infections and liver tissue regeneration.

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