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# Can-Fite Submitted its Protocol for a Phase IIb Clinical Study of CF101 in Rheumatoid Arthritis Patients to the US Food and Drug Administration (FDA). The Multinational Phase IIb Clinical Study Scheduled to Begin in Q2 of 2006

Can-Fite BioPharma announced today that it submitted a draft protocol for a Phase IIb clinical study in rheumatoid arthritis (RA) patients to the US FDA. Can-Fite has an open IND for RA in the US since early January. Under this open IND the company is currently conducting a CF101 – methotrexate (MTX) drug interaction study in RA patients preparatory to the Phase IIb study that is scheduled to begin within a few months.

The company's Phase IIb study will be a multi-national study that will be conducted in the US, Europe and Israel. A total of about 250 patients are expected to be enrolled in this study which will examine the efficacy of CF101 in combination with methotrexate in treating RA patients.

Prof. Pnina Fishman, the CEO of Can-Fite states that "submission of the draft Phase IIb protocol to the FDA within the framework of our IND, which was already approved by the FDA, is a major step towards the start of our Phase IIb study. We trust that this study will provide a clear evidence for the efficacy of CF101. The few recent commentaries that appeared in some major publications that mentioned CF101 as one of the promising RA drugs in development, show that our development efforts are receiving proper credit scientific and clinical communities worldwide".

The company recently presented its findings from an early Phase II clinical study of CF101 in rheumatoid arthritis patients during the Annual Scientific Meeting of the American College of Rheumatology (ACR), held in San Diego in November 12 – 17, 2005. These findings showed that CF101, given orally, twice daily, was active in reducing disease symptoms in these patients, as measured by standard ACR criteria. Following the meeting a report on novel drugs that were presented at the ACR meeting appeared online in an article published by CIAOMed.org, a premier source of cutting edge scientific updates to rheumatologist and related medical disciplines. In this report which is dated Nov 17, Can-Fite's CF101 clinical data received centerpiece coverage, as one of the promising new drugs that were presented at the San Diego ACR meeting (see http://www.ciaomed.org/articles.cfm?articleID=449). CF101 was also listed among the 15 leading drugs in development for RA in a recent review

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**About Can-Fite**

Can-Fite BioPharma Ltd. is a public company, traded on the Tel-Aviv Stock Exchange that is headquartered in Petach-Tikva, Israel. The company, which began its operations at the end of 2000, was founded based on the work by Professor Pnina Fishman, formerly a Tumor Immunologist in the Rabin Medical Center and currently the company's CEO, together with Dr Ilan Cohn, Patent Attorney and Senior Partner at Reinhold Cohn and Partners, a leading Israeli Patent Attorney firm. The Company has research laboratories and offices in Israel. The Company's lead drug, CF101, for the treatment of rheumatoid arthritis is currently in Phase II clinical trials and to date went through clinical trials in the USA, UK and Israel.

**About CF101**

CF101 is a small molecule, which is administered to patients orally. This drug, which is developed for the treatment of rheumatoid arthritis, was tested to date in clinical trials in the USA, UK and Israel. The drug is active against a wide variety of autoimmune and cancer diseases and has a preferential safety profile. The drug's main advantage is in its ability to specifically attack pathological cells without affecting healthy ones. In addition, the fact that the drug is administered orally in the form of a capsule creates a huge advantage vs. current treatments which are administered by IV infusion or injection, at much higher costs.

Rheumatoid arthritis (RA) is a severe and chronic autoimmune disease that affects more than 1% of the population in the Western World. The disease is characterized mainly by inflammation of the lining, or synovium, of the joints that can lead to long-term joint damage, resulting in chronic pain, loss of function and disability. The market of disease modifying anti-rheumatic drugs is estimated to be about US$ 5 billion and is expected to rise to about $7 billion by 2007.

More information can be found at www.canfite.com

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