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Press Release

Can-Fite Announces Positive Results from its Phase II Trial Treating Keratoconjunctivitis Sicca (Dry Eye Syndrome) with CF101

Dry Eye affects more than 30 million people in the US alone

Can-Fite BioPharma, an Israeli Biopharmaceutical company, announced today that its 80-patient Phase II clinical study using CF101 to treat patients with moderate to severe Dry Eye Syndrome had successfully met the primary efficacy endpoint. Patients in this masked study were randomly assigned to either 1 mg of CF101 or matching placebo; drug was taken orally as a monotherapy for 12 weeks. The 12 week duration is one that Can-Fite has used in other trials of CF101 as an anti-inflammatory agent, and is similarly a common one for Phase II trials of Keratoconjunctivitis Sicca. The patient group receiving CF101 demonstrated statistically significant improvement in superficial punctate keratitis, relative to the placebo group, as measured by fluorescein staining. This sensitive and prevalent measure of corneal disease was prospectively defined as a primary study endpoint, thus demonstrating the ability of orally administered CF101 to exert beneficial effects on ocular surface inflammation. An improvement in additional study parameters was also observed. CF101 was safe and well tolerated during the study period.

These findings supply evidence for the efficacy of CF101 alone as a systemic anti-inflammatory drug. Recently Can-Fite announced that a Phase IIb study with CF101, in combination with methotrexate, failed to meet its primary end point in the treatment of Rheumatoid Arthritis, most probably due to lack of efficacy in the combined treatment. A Phase II study in patients with Psoriasis is ongoing also utilizing CF101 as monotherapy, and based on Can-Fite's estimations, data will be released during Q3 2009.

Dry Eye Syndrome affects a large proportion of the general population, including contact lens users and postmenopausal women, and is also associated with Rheumatoid Arthritis. Based on published data, Dry Eye Syndrome affects more than 30 million people in the US alone, and the market for treatments is estimated at about US\$ 1 billion. In addition, it was also suggested by the scientific community that developing effective ethical drugs for the treatment of Dry Eye Syndrome may increase the market size. Can-Fite entered the development of CF101 for this indication after learning that, during a Phase IIa rheumatoid arthritis trial, several patients reported a significant improvement in their Dry Eye Symptoms following treatment with CF101 as a monotherapy.

An additional interesting finding of the current Dry Eye study demonstrated a decrease in the intra ocular pressure in patients who were treated with CF101. This

finding may pave the way towards additional clinical applications of adenosine A3 agonists in the ophthalmology arena such as Glaucoma.

Prof. Isaac Avni, Director of Ophthalmology, Assaf-Harofea Medical Center and the study principal investigator, said today "there is a linear increase in the number of patients suffering from Dry Eye Syndrome all over the world and we are very happy with the positive results of this Phase II study. In addition to the impressive data demonstrating an improvement in the signs and symptoms of Dry Eye Syndrome, I am very excited by the data showing that CF101 decreased the intraocular pressure in the patients participated in this study".

Prof. Pnina Fishman, CEO of Can-Fite, said today "we are very enthusiastic about the results of this Phase II study demonstrating efficacy of CF101 in the Dry Eye Syndrome. The performance of CF101 as a stand alone drug supports the scientific rationale of the A3 adenosine receptor target. These are promising results which render us to continue with the drug development program of CF101 in the ophthalmology field".

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 small 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 Psoriasis (Phase II). Can-Fite develops CF102 for the treatment of liver conditions, including liver cancer and hepatitis infections.

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