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Press Release

Can-Fite BioPharma Received Israeli MoH Approval to Conduct a Clinical Trial Evaluating the Efficacy of CF101 in Patients with Dry Eye Syndrome

Dry Eye Syndrome affects over 30 million people worldwide; Can-Fite estimates current market at approx. US\$ 1 billion

Can-Fite, a biotechnology company traded on the Tel Aviv Stock Exchange, received approval from the Israeli Ministry of Health (MoH) to conduct phase II clinical trial with orally-administered CF101 in the treatment of dry eye syndrome (known as "keratoconjunctivitis sicca", or KCS).

The trial will include approximately 50 patients at medical centers in Israel. The trial protocol and the results will also be reported to the US FDA.

Can-Fite's CF101 is a targeted drug that specifically attacks diseased or pathologic cells without compromising normal body systems, and therefore has shown a favorable safety profile to date. CF101 is based on a scientific concept suggesting that the target of the drug (A3 adenosine receptor) is highly expressed on the surface of pathologic cells. The Company's phase IIa clinical trial with CF101 in the treatment of rheumatoid arthritis (RA) has shown a significant correlation between the presence of the target on the affected cells and a positive response to the drug.

KCS affects a broad segment of the population, including contact lens users and postmenopausal women. It is also associated with RA and related immunologic diseases, which is referred to as Sjogren's Syndrome. Can-Fite has commenced drug development for this indication after several patients in a phase IIa RA trial reported a substantial improvement in their dry eye symptoms and in tear production following treatment with CF101.

The main cause of KCS is an inflammatory process in the lacrimal gland and ocular surface. CF101 has an anti-inflammatory effect; therefore, its mechanism of activity, which has been extensively studied by Company scientists, supports potential use of the drug in the treatment of dry eye symptoms. The current standard therapy for KCS is eye drops taken multiple times a day. These eye drops neither treat the cause nor alter the course of the disease, but are only useful for lubrication and symptomatic relief.

Prof. Pnina Fishman, CEO of Can-Fite, said today: "There are currently over 30 million people worldwide suffering from Dry Eye Syndrome. To date, no simple effective solution has been found to alleviate their distress, and therefore there is a real need to develop medication for the treatment of this syndrome. Oral tablets could free patients from recurrent use of eye drops and enhance treatment efficacy. We hope and believe that CF101 will be proven effective in the treatment of this disorder and provide relief to millions of patients."

Can-Fite recently reported further progress with CF101 in the treatment of RA and announced the successful completion of a study evaluating the interactions between CF101 and food. This type of trial is one in a series of trials announced by the Company in its share prospectus as a means of expediting the transition into phase III clinical trials in the US with CF101 in the treatment of RA.

Can-Fite, whose shares were first issued in September 2005, has evolved within a short period of time from a single-product to a multi-product company with a development pipeline that includes drugs for various clinical applications. Apart from the RA indication, the Company is also developing CF101 for the treatment of KCS, and explores the possibility of entering the development of additional indications.

CAN-FITE BIOPHARMA LTD is a public company listed on the Tel Aviv Stock Exchange. The Company, which commenced business activity in 2000, was co-founded by investigator Prof. Pnina Fishman and patent attorney Dr. Ilan Cohn. The Company focuses on the development of molecule-based drugs that inhibit the development of cancer and inflammatory cells. The Company's lead drug, CF101, is being developed for the treatment of RA, and is currently in Phase II clinical trials. The potential market for RA treatments is estimated at approx. US\$ 7 billion per annum and is projected to grow at an annual rate of approx. 20%. **The current market for KCS medication is approx. US\$ 1 billion per annum.**

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