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CAN-FITE BioPharma Ltd.

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Press Release

CAN-FITE BIOPHARMA ANNOUNCES THE INITATION OF PHASE 3 IN DRY EYE SYNDROME

Petah-Tikva, Israel, September 6, 2010: Can-Fite BioPharma Ltd (TASE:CFBI), a biotechnology company traded on the Tel Aviv Stock Exchange, announced today that it has opened an Investigational New Drug application (IND) with the US-FDA for a Phase 3 study of its lead drug, CF101, in patients with moderate to severe Dry Eye Syndrome.

In an earlier Phase 2 study, in which CF101 taken orally as a monotherapy for 12 weeks, a statistically significant benefit in the clearing of fluorescein staining in the nasal, temporal, pupillary and inferior parts of the cornea was documented. CF101 was found to be safe and well tolerated during this study period. In this study, a decrease in intra-ocular pressure was also observed in patients with dry eye. These findings have prompted the company to initiate a Phase 2 clinical study in patients with Glaucoma which is currently ongoing with CF101.

Dr. Pnina Fishman, Can-Fite's CEO, said, "We are extremely gratified that our scientific and clinical efforts have culminated in this important milestone for the company. As part of this IND, we submitted a registration-quality Phase 3 clinical protocol for the treatment of patients with moderate-to-severe Dry Eye as defined by signs and symptoms. Following review by the FDA, we are now confident that this protocol has the appropriate design features, clinical endpoints, and statistical power to allow it to serve as the first of two Phase 3 trials that will lead to the approval of CF101 for this indication."

The randomized, double-masked, trial will compare 2 doses of CF101 to placebo. Approximately 240 patients will be enrolled at multiple centers; they will be treated for 24 weeks. The main outcome assessments (clinical endpoints) are improvement of corneal fluorescein staining (which is a measure of ocular surface inflammation), tear production, and dry eye symptom score.

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 a safe and effective treatment is estimated at US$ 2 billion. Can-Fite entered the development of CF101 for this indication after learning that, during a Phase 2a rheumatoid arthritis trial, several patients reported a significant improvement in their Dry Eye Symptoms following treatment with CF101 as a monotherapy.

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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 A3 adenosine receptors of cancerous or inflammatory cells and inhibit their development.

For more details:

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