



Can-Fite BioPharma announces successful results of its Phase I/II Liver Cancer study with its CF102 Drug; the Study achieved the primary and secondary endpoints

Petah Tikva, Israel, January 3rd 2012: Can-Fite BioPharma (TASE: CFBI) announced today the successful results of the Phase 1/2 study of its drug candidate CF102 in the treatment of hepatocellular carcinoma (HCC).

The company also announced today that a separate phase 1/2 study in patients with Hepatitis C (HCV) reached the study's main objectives of safety and pharmacokinetic behavior.

The HCC study which was conducted under the supervision of Dr. Salomon M. Stemmer, Institute of Oncology, Davidoff Center, Rabin Medical Center, included 18 patients with HCC, most of them had failed prior treatment with Sorafenib (Nexavar), the only currently approved drug for this indication. The primary study objectives were to evaluate the safety profile of long-term administration of CF102 at 3 different dose levels in patients with HCC, and to determine the pharmacokinetic behavior of CF102 in this patient population. The secondary objective of the trial was to document evidence of clinical efficacy and to look at the correlation between A3 adenosine receptor expression levels at base line and patients' response to CF102.

The study data demonstrate that the trial objectives were successfully achieved, showing a very favorable safety profile for CF102 in a patient population with hepatocellular carcinoma and Child-Pugh cirrhosis classes A and B. In addition, the median overall survival time was 7.8 months, which is very encouraging data given that most patients were treated in the second-line setting and some were Child-Pugh class B. Remarkably, the median overall survival time of the Child-Pugh B patients was 9.4 months, the longest overall survival time that has been reported in the literature for this patient population.

Out of the 18 patients, 9 were infected with Hepatitis C. In 7 patients treated with the high CF102 dosages, a reduction in HCV load was observed.

According to Dr. Keith Stuart, MD, Chairman, Department of Hematology and Oncology, Lahey Clinic Medical Center, Professor of Medicine, Tufts University School of Medicine: "The safety and efficacy data of the CF102 Liver Cancer study are impressive and encouraging in the context of other investigational drugs. Therefore, I would recommend further clinical development of this drug for the treatment of patients with hepatocellular carcinoma. I hope that the present data will be reproducible and that patients could benefit from this drug".



In parallel, the company also announced today that a separate phase 1/2 study in patients with Hepatitis C (HCV) reached the study's primary objectives of safety and pharmacokinetic behavior. However, a reduction in the HCV viral load was not observed. It should be noted that patients on this study were treated for several months only with the low dose of CF102.

According to Dr. Pnina Fishman, the company CEO, "We are very pleased that the study achieved all of its objectives in patients with HCC, most of whom had failed prior treatment with Nexavar. The impressive results in the HCC study encourage us to continue development of CF102 in patients with Liver Cancer. We will focus on this disease and will continue to observe the viral load of HCC patients who also suffer from HCV".

CF102 is a small orally bioavailable drug which bind with high affinity and selectivity to the A3 adenosine receptor. The latter is highly expressed in tumor cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug. The drug induces a robust anti-tumor effect via de-regulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells. agonist at the A3 adenosine receptor

About Can-Fite Biopharma Ltd.

Can-Fite Biopharma Ltd is a public company, trading on the Tel Aviv Stock Exchange. The company, which commenced business activity on 2000, was founded by Prof Pnina Fishman, researcher in the Rabin Medical Center, and Dr Ilan Cohen, patent attorney and senior partner at Reinhold Cohen Patent Attorneys. Prof Fishman serves as CEO of the company. The company was founded on the basis of Prof Fishman's scientific findings, and is focused on the development of small molecule drugs, ligands to the A3 adenosine receptor. The latter mediates anti-inflammatory and anti-cancer effects and is suggested as a biological predictive marker. The company's lead drug, CF101, is in advanced clinical development for the treatment of autoimmune inflammatory diseases. The CF102 drug candidate is being developed for the treatment of liver diseases. Can-Fite has a wealth of clinical experience: to date, more than 700 patients have participated in clinical trials conducted by the company. Can-Fite recently licensed its activity in the ophthalmic field to OphthaliX Inc.

About OphthaliX Inc (formerly Denali Concrete Management Inc).

OphthaliX Inc. (OTCBB: DCMG) is an advanced clinical-stage biopharmaceutical company focused on developing therapeutic products for the treatment of ophthalmic disorders. Denali's product candidate, CF101, is being developed to treat three ophthalmic indications: dry eye syndrome; glaucoma and uveitis. Can-Fite holds 82.3% in OphthaliX Inc.



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