FDA grants Orphan Drug Status for CF102 for the Treatment of Hepatocellular Carcinoma

Petah Tikva, Israel, February 22nd 2012: Can-Fite BioPharma (TASE: CFBI) announced today that the US Food and Drug Administration (FDA) has granted Orphan Drug Status for its drug candidate, CF102, for the treatment of hepatocellular carcinoma (primary liver cancer).

Can-Fite CEO Prof. Pnina Fishman commented, "Obtaining Orphan Drug Status for CF102 for the treatment of hepatocellular carcinoma is an important regulatory step in the drug's development pathway, providing numerous incentives and protections that will facilitate its development for liver cancer. This designation is an additional important milestone in the development of CF102, and follows the successful phase I/II results published last month".

Orphan Drug Status is granted for drugs being developed for treating diseases that affect a small number of people. In the US, the figure is 200,000 people. The status provides, subject to the completion of the development of the drug and obtaining a marketing approval from the FDA, various incentives and preferences for the research, production and marketing of these drugs, which may include seven years marketing exclusivity from the date of approval, tax breaks, and exemptions on FDA fees.

Earlier this year, Can-Fite announced successful results of the Phase I/II study of CF102 for the treatment of hepatocellular carcinoma. The study data demonstrate that the trial objectives were successfully achieved, demonstrating 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 very encouraging given that most patients were treated in the second-line setting and some were Child-Pugh class B. Another finding indicated that the A3 adenosine receptor, which is the target of CF102, can serve as a biomarker to predict the patients' reaction to treatment with CF102.

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.

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.

OphthaliX Inc. (OTCBB: OPLI) is an advanced clinical-stage biopharmaceutical company focused on developing therapeutic products for the treatment of ophthalmic disorders. OphthaliX'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.

Contact:

Pnina Fishman, Chief Executive Officer
Tel: +972-3-9241114
Email: pnina@canfite.com