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Can-Fite Completes Phase II Study Design for CF102 in the Treatment of NASH/NAFLD

- NASH/NAFLD are the leading cause of liver disease in Western countries

- $35 billion estimated global market for NASH by 2025

- Compelling pre-clinical data indicate hepato-protective drug CF102 may be effective in treating NASH/NAFLD

PETACH TIKVA, Israel, July 25, 2016 /PRNewswire/ --Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, announced today that it completed the protocol design for its upcoming Phase II trial of its drug candidate CF102 in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH).

NAFLD is characterized by excess fat accumulation in the form of triglycerides (steatosis) in the liver. According to a recent study published in Hepatology, an estimated 25% of the population in the U.S. has NAFLD, with a higher prevalence in people with type II diabetes. Incidence is increasing based on rising obesity rates. NAFLD includes a range of liver diseases, with NASH being the more advanced form, manifesting as hepatic injury and inflammation. According to the NIH, the incidence of NASH in the U.S. is believed to affect 2-5% of the population. The spectrum of NAFLDs resembles alcoholic liver disease; however, they occur in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer.

By 2025, Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach $35-40 billion in size. As of today, while there are several companies developing drugs to treat NAFLD/NASH that are in preclinical and clinical development, no specific U.S. Food and Drug Administration (FDA) approved treatment exists.

According to the study design, Can-Fite's Phase II study, which was designed by world renowned Key Opinion Leaders in the field of liver diseases, will be a multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of CF102 in the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD). The study will enroll approximately 75 patients and will have three arms, including two different dosages of CF102 and a placebo, given via oral tablets twice daily. The study's primary endpoints will be percent change from baseline in liver triglyceride (fat) concentration measured by nuclear magnetic resonance spectroscopy (NMRS) and safety. Secondary endpoints include the effects of CF102 on metabolic abnormalities in patients with NAFLD;

the effects of CF102 on relevant NAFLD related biomarkers; and an assessment of the pharmacokinetics (PK) of CF102 in patients with NAFLD. The A3 adenosine receptor (A3AR) biomarker will be evaluated prior to treatment and its correlation to patients' response to the drug will be analyzed upon study conclusion. The study will be conducted in leading medical centers in Israel and is expected to be submitted to IRBs in the fourth quarter of this year.

"We are very pleased the Phase II study design for the indication of NAFLD/NASH is completed and we look forward to commencing this important study. Based on the good safety data we have on CF102 from our current Phase II trial in liver cancer, its anti-inflammatory as well as liver protective profile, and the positive pre-clinical data in NASH models, we believe patients with NAFLD may benefit from CF102," stated Can-Fite CEO Pnina Fishman.

CF102 is currently being evaluated in a Phase II study for the treatment of hepatocellular carcinoma (HCC). Recent preclinical studies of CF102 revealed its capability to improve liver pathology in a NAFLD animal model of NASH including data showing a statistically significant reduction in NAFLD activity score compared to placebo.

About CF102

CF102 is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). A3AR 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. In Can-Fite's pre-clinical and clinical studies, CF102 has demonstrated a robust anti-tumor effect via deregulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI) is an advanced clinical stage drug development Company with a platform technology that is designed to address multi-billion dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is scheduled to enter Phase III trials in 2016 for two indications, rheumatoid arthritis and psoriasis. The rheumatoid arthritis Phase III protocol has recently been agreed with EMA. Can-Fite's liver cancer drug CF102 is in Phase II trials for patients with liver cancer and is slated to enter Phase II for the treatment of non-alcoholic steatohepatitis (NASH). CF102 has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. CF602, the Company's third drug candidate, has shown efficacy in the treatment of erectile dysfunction in preclinical studies and is being prepared for an IND submission to the FDA and a Phase I trial. These drugs have an excellent safety profile with experience in over 1,000 patients in clinical studies to date. For more information please visit: www.can-fite.com.

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