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Can-Fite Submits Protocol for Phase II Trial of CF102 in the Treatment of NAFLD/NASH

- Leading Israeli medical institutions Hadassah and Rabin Medical Centers to be included in the trial

- Study to enroll 60 patients with primary endpoint of reducing liver fat

- $35 billion estimated treatment market by 2025

PETACH TIKVA, Israel, Oct. 13, 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 and liver diseases, cancer, and sexual dysfunction, today announced it has submitted the clinical trial protocol for its Phase II study of CF102 in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH), to a leading Institutional Review Board (IRB) in Israel. Top medical centers in Israel, including Hadassah Medical Center and Rabin Medical Center are expected to participate in the planned study by enrolling and treating patients.

"We are eager to commence our Phase II study in NAFLD/NASH, an indication for which there is no U.S. FDA approved drug. We view the submission of our clinical trial protocol as a major step forward," stated Can-Fite CEO Dr. Pnina Fishman.

Based on the protocol that was submitted, Can-Fite's Phase II study, 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 NAFLD/NASH. The study will enroll approximately 60 patients with NAFLD, with or without NASH, 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 to be evaluated are the effects of CF102 on metabolic abnormalities in subjects with NAFLD, including body weight, waist circumference, serum triglyceride and high-density lipoprotein cholesterol levels, and serum liver transaminase. In addition, an assessment of the pharmacokinetics (PK) of CF102 and 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. Furthermore, the exploratory objective of this study is to evaluate the effects of CF102 on relevant biomarkers, such as adiponectin, leptin, C-reactive protein (CRP), and liver stiffness as determined by Fibroscan. The trial design is based on preclinical studies showing CF102's efficacy in reducing liver fat in NASH models as compared to placebo, improving liver function, and regenerating liver cells.

Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach $35-

40 billion in size by 2025.

About NAFLD/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.

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 diseased 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. Based on preclinical data showing CF102 has strong liver protective properties, Can-Fite intends to initiate a Phase II study in NASH. Can-Fite has received Orphan Drug Designation for CF102 in Europe and the U.S., as well as Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma.

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 the European Medicines Agency. 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.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from

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