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Can-Fite Receives IRB Approval to Commence Patient Enrollment in Phase II NAFLD/NASH Trial in Q1 2017

Compelling unmet need for NAFLD/NASH drug due to lack of FDA approved drug for the indication and an estimated $35 billion treatment market by 2025

PETACH TIKVA, Israel, Jan. 9, 2017 /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 received approval to commence patient enrollment in a Phase II study of its liver drug candidate Namodenoson (CF102) in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH). Approval came from the Institutional Review Boards (IRBs) of Hadassah Medical Center and Rabin Medical Center, two leading medical institutions in Israel where the study will be conducted.

"Based on the swift and positive response from these leading medical institutions, we are ready to commence patient enrollment in the first quarter of 2017 in our Phase II NAFLD/NASH trial," stated Can-Fite CEO Dr. Pnina Fishman. "A growing body of preclinical data point to the potential efficacy of Namodenoson in the treatment of NAFLD/NASH and we are eager to validate these results in humans."

The approved clinical protocol is a Phase II multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of Namodenoson in the treatment of NAFLD/NASH. Approximately 60 patients with NAFLD, with or without NASH, will be enrolled in three arms, including two different dosages of Namodenoson 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 Namodenoson 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 Namodenoson 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 Namodenoson 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 Namodenoson's efficacy in reducing liver fat in NASH models as compared to placebo, improving liver function, and regenerating liver cells.

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 Namodenoson (CF102)

Namodenoson 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, Namodenoson 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 Namodenoson has strong liver protective properties, Can-Fite intends to initiate a Phase II study in NASH. Can-Fite has received Orphan Drug Designation for Namodenoson 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 2017 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 Namodenoson 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). Namodenoson 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. Namodenoson 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 time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or

"anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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