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New Preclinical Data Show Can-Fite's Namodenoson (CF102) Inhibits Liver Fibrosis -- Supports Potential Efficacy in Treatment of NASH

Phase II trial to treat NAFLD/NASH expected to commence in 2017

PETACH TIKVA, Israel, Dec. 16, 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, today announced that new preclinical data show its liver disease drug candidate Namodenoson (CF102) inhibited, in a dose dependent manner, the growth and proliferation of the liver fibrosis cells. This outcome suggests the anti-fibrotic effect of the drug and supports its development as an agent to combat non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH).

Pre-clinical studies which evaluated the effects of Namodenoson on fibrogenic hepatic stellate cells were conducted under the supervision of Prof. Rifaat Safadi M.D., a Key Opinion Leader in the field of liver diseases, and Director of Liver Unit, Institute of Gastroenterology and Liver Diseases, Hadassah University Hospital, Ein Kerem.

Prof. Safadi commented, "Today there is a huge market need for drugs that fight the worldwide NASH epidemic. Lowering liver fat content and fibrosis are the main unmet needs in NASH. This is especially so for a drug candidate with the profile of Namodenoson, which recognizes the difference between diseased and normal cells, and targets only the diseased cells through the specific A3 adenosine receptor. This precision targeting is designed to lead to higher efficacy and safety by leaving healthy cells unaffected. We are all looking for drugs with this profile to treat NASH."

"These latest study results add to the growing body of data that demonstrate Namodenoson's potential efficacy in NAFLD and NASH, indications for which there is currently no FDA approved drug. We are advancing Namodenoson into a Phase II trial that we expect to commence in the coming months through leading medical institutions in Israel," stated Can-Fite CEO Dr. Pnina Fishman.

By 2025, the addressable pharmaceutical market for NASH is estimated to reach \$35-40 billion.

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 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 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

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