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# Can-Fite's Liver Protective Drug Namodenoson Enters Phase II Trial for Treatment of NAFLD/NASH

- **\$35 Billion treatment market by 2025 with need for an FDA approved drug**
- **Phase II trial's estimated cost is under \$1 Million**
- **Namodenoson drug supply ready and IRBs have approved protocol for patient recruitment**

PETACH TIKVA, Israel, May 3, 2017 /PRNewswire/ --[Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, today provided an update on a Phase II clinical trial to evaluate its liver drug candidate Namodenoson (CF102) in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH).

Namodenoson drug supply for the Phase II trial has been paid for and is ready to be administered to patients. Institutional Review Boards (IRBs) at Hadassah Medical Center and Rabin Medical Center, two leading medical institutions in Israel where the study will be conducted, have approved the trial protocol. Can-Fite estimates the cost of this Phase II trial to be less than \$1 million.

Robust pre-clinical data demonstrated that Namodenoson has hepato-protective effects; helps support liver function by reducing liver fat in NASH models as compared to placebo; inhibits and prevents the progression of liver fibrosis; improves liver function; and regenerates liver cells.

"We believe that Namodenoson's high safety profile, based on robust clinical and pre-clinical findings, positions our liver drug as a promising candidate among the drugs currently under development for NASH in the market today," stated Can-Fite CEO Dr. Prina Fishman.

"NAFLD and NASH are now widely recognized as a significant public health risk, driven by growing rates of diabetes and obesity. Can-Fite and other leading pharmaceutical and biotechnology companies are working hard to bring safe and effective treatments to this market in need."

"Having concluded all of our preparations for the Phase II NAFLD/NASH trial, we look forward to announcing the commencement of patient enrollment in the coming weeks," Dr. Fishman concluded.

Can-Fite will present its latest findings on Namodenoson's role in liver function at the <sup>st</sup>

International [Conference](#) on Fatty Liver in Seville, Spain on June 1-3, 2017. Recent findings include:

- Namodenoson prevented liver (hepatic) fibrosis progression in a mouse model of liver fibrosis. Liver fibrosis is the excessive accumulation of scar tissue resulting from ongoing inflammation. It can result in diminished blood flow throughout the liver and is associated with NAFLD. The Namodenoson treated group exhibited normal liver under macroscopic view, no accumulation of fluid (ascites), a low fibrosis profile, and lower serum levels of transaminases as compared to the control group.
- In a dose depending manner, Namodenoson inhibited the growth and proliferation of the liver fibrosis cells in pre-clinical studies on fibrogenic hepatic stellate cells.
- Namodenoson protected the liver from ischemia/reperfusion injury and regenerated liver cells following partial hepatectomy. Liver surgery, liver transplantation, and toxic liver conditions such as NASH can lead to injury of the liver characterized by inflammatory conditions and liver cell death. Pre-clinical studies showed that Namodenoson protected the liver against ischemic reperfusion manifested by a statistically significant ( $p < 0.05$ ) reduction in key liver enzymes, SGOT and SGPT. In addition, in studies where partial liver hepatectomy was conducted, a 45% increase in the regeneration rate of the remaining liver was observed after treatment with Namodenoson, compared to placebo which regenerated only by 24%.
- Namodenoson improved liver pathology in a NAFLD/diabetes animal model of NASH. Namodenoson had a statistically significant reduction in NAFLD activity score compared to placebo. Parameters of improvement included reduced liver-to-body weight compared to placebo; decreased plasma ALT and triglycerides levels in the livers of the NASH-model compared to placebo; improved pathology in animals receiving Namodenoson vs. placebo as evidenced through representative photomicrographs of H&E-stained liver sections showed; and liver sections from the placebo group exhibited severe micro- and macrovesicular fat deposits, hepatocellular ballooning and inflammatory cell infiltration, whereas the Namodenoson treated group showed a significant decrease in steatosis, ballooning and lobular inflammation compared to the placebo group.
- In a concluded Phase I/II human trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, Namodenoson has shown to have a favorable safety profile and lack of hepatotoxicity. Can-Fite has an ongoing Phase II study of 78 patients with HCC.

Under the approved clinical protocol, the Phase II multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of Namodenoson in the treatment of NAFLD/NASH will enroll approximately 60 patients with NAFLD, with or without NASH. The study will have three arms, including two different dosages of Namodenoson and a placebo, given via oral tablets twice daily. The study's primary endpoints are 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.

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 17%-33% 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 autoimmune-inflammatory indications, oncology and liver diseases as well as sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is headed into Phase III trials for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug Namodenoson is in a Phase II trial for patients with liver cancer and is slated to enter another Phase II for the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to 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. 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](http://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, market risks and uncertainties and Can-Fite's ability to satisfy all the conditions to the closing of the proposed offering, 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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