

# **New Preclinical Data Show Can-Fite's Namodenoson (CF102) Prevents Progression of Liver Fibrosis**

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

**- Lowering liver fat content and fibrosis are the main unmet needs in NASH, according to KOL Dr. Rifaat Safadi**

PETACH TIKVA, Israel, Feb. 28, 2017 /PRNewswire/ -- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, today announced new data that show its liver disease drug candidate Namodenoson (CF102) prevented liver (hepatic) fibrosis progression in preclinical studies.

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

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.

Recent preclinical studies in a mouse model of liver fibrosis demonstrated the anti-fibrotic effects of Namodenoson. 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 addition, liver protein extracts and mRNA for the alpha smooth muscle actin showed a significant anti-fibrotic effect in the Namodenoson treated group as compared to the control group.

These studies were conducted by a third party 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, "Lowering liver fat content and fibrosis are the main unmet needs in NASH. Today there is a huge market need for drugs that fight the worldwide NASH epidemic."

"Namodenoson is uniquely compelling for its potential to treat NAFLD and NASH because its safety profile has already been de-risked, increasing the likelihood it can advance through late stage trials and into clinical use for this large and unmet need," Dr. Safadi added. "In

general, there is significant development risk for new potential drugs in development due to safety risks including drug induced liver injury (DILI), drug-to-drug interactions (DDI), and metabolites in safety testing (MIST). Namodenoson, however, has demonstrated a good safety profile and is low or negative for DILI, DDI and MIST."

"In addition, Namodenoson 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," concluded Dr. Safadi.

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 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](http://www.can-fite.com).

#### Forward-Looking Statements

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/new-preclinical-data-show-can-fites-namodenoson-cf102-prevents-progression-of-liver-fibrosis-300414630.html>

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