# New Preclinical Data on Can-Fite's Namodenoson to be Presented at 1st International Conference on Fatty Liver in Seville, Spain on June 2, 2017

- Data show Namodenoson both prevents and inhibits liver fibrosis
- Namodenoson is to be evaluated in upcoming Phase II trial for the treatment of NAFLD/NASH

PETACH TIKVA, Israel, June 1, 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 announced that Professor Rifaat Safadi M.D. will present new preclinical data on Can-Fite's liver drug candidate Namodenoson in a poster titled, "Namodenoson (CF102) Prevents Progression of Liver Fibrosis" on June 2, 2017 at the 1<sup>st</sup> International Conference on Fatty Liver in Seville, Spain which takes place from June 1-3, 2017.

A Key Opinion Leader in the field of liver diseases, Prof. Safadi co-authored the poster, based on two experimental animal models. He is Director of Liver Unit, Institute of Gastroenterology and Liver Diseases, Hadassah University Hospital in Israel.

The study evaluated the effects of Namodenoson on two different mouse models where in the CCL4 one, the mice were treated with the drug in conjunction with model induction, whereas in the NASH model, disease was first induced and then treatment was initiated via oral administration. Data show that Namodenoson both prevented progression and inhibited liver fibrosis to obtain fibrosis regression.

<u>Prevention of Fibrosis:</u> Namodenoson treated mice showed normal macroscopic liver with no ascites, reduced liver to body weight ratio as well as significant decrease in ALT serum levels and alpha-smooth muscle actin ( $\alpha$ -SMA) compared to placebo treated animals.

Inhibition of Fibrosis: A statistically significant reduction in the non-alcoholic fatty liver disease (NAFLD) score was demonstrated in the Namodenoson treated NASH models. Namodenoson markedly decreased the CK-18 marker, a Mallory's hyaline structure in hepatocytes, and increased adipoenctin expression, an anti-fibrogenic and anti-inflammatory protein.

Prof. Safadi stated, "Data show that treatment with Namodenoson prevented fibrosis progression in the hepatic fibrosis mouse model, as well as inhibiting fibrosis in the NASH mouse model. I believe these data, together with the well- established hepato-protective characteristics of Namodenoson, support its further development as a drug candidate. There is a huge market need for drugs that fight the worldwide NASH epidemic. I believe

Namodenoson is a strong candidate to help fill this need because the drug recognizes the difference between diseased and normal cells, and targets only the diseased cells through the specific A3 adenosine receptor. My team and I at Hadassah Medical Center look forward to participating in the upcoming Phase II NAFLD/NASH study."

"We are very encouraged by the growing body of evidence showing Namodenoson's liver protective properties. These data support our upcoming Phase II NAFLD/NASH trial, as well our Phase II liver cancer trial which is nearing completion," stated Can-Fite CEO Dr. Pnina Fishman. "We are honored to have Dr. Safadi, a leading expert in the field of liver disease participate in investigating Namodenoson."

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 multibillion 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: <a href="https://www.can-fite.com">www.can-fite.com</a>.

## **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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To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/new-preclinical-data-on-can-fites-namodenoson-to-be-presented-at-1st-international-conference-on-fatty-liver-in-seville-spain-on-june-2-2017-300466784.html

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