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# Can-Fite Presented NASH Phase II Namodenoson Data at a Late Breaking Session of the American Association for the Study of Liver Diseases (AASLD) Conference

***Dr. Safadi, the study's Principal Investigator: "Namodenoson's very impressive study data may result in a promising drug for the treatment of NAFLD/NASH due to the combination of good efficacy and favorable safety."***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd](#). (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced that Dr. Rifaat Safadi, Principal Investigator of the Company's Phase II study of Namodenoson in the treatment of NAFLD/NASH delivered a late-breaking oral presentation at the AASLD conference, The Liver Meeting Digital Experience™ 2020.

Titled "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Dose-Finding Study Of The Efficacy And Safety Of Namodenoson (CF102), An A3 Adenosine Receptor (A3AR) Agonist, In Treating Non-Alcoholic Fatty Liver Disease (NAFLD) And Non-Alcoholic Steatohepatitis (NASH)" the oral presentation was given on Sunday, November 15 by Dr. Safadi, Head of the Liver Unit, Gastroenterology and Liver Diseases, Division of Medicine at Hadassah Medical Center, Professor of Internal Medicine, Bowel, Liver Disease, and Metabolic Syndrome at Hebrew University in Israel.

The double-blind, placebo-controlled, dose-finding efficacy and safety study enrolled 60 patients with NAFLD with or without NASH. Patients with evidence of an active inflammation were treated twice daily with 12.5 mg (n=21) or 25 mg (n=19) of oral Namodenoson vs. placebo (n=20). The patients were treated for 12 weeks and followed-up until week 16. As a result of the study, 25 mg was determined to be the optimal dose.

Data presented during the oral presentation included:

- Anti-Inflammatory effect – a significant decrease in the liver enzymes ALT and AST and significant improvement in the positive cytokine adiponectin was recorded in the Namodenoson 25 mg treated group
- Reduced liver fat content - manifested by a significant reduction in % of liver fat volume assessed by MRI-PDFF and a decrease in the Controlled Attenuation Parameter (CAP – score  $\geq$  331) measured by FibroScan in the Namodenoson 25 mg group
- Decrease in FIB-4 and FAST – non-invasive tests showed anti-fibrosis effect in

Namodenoson 25 mg group

- Decrease in body weight - a linear decrease in body weight was recorded in the 25 mg and 12.5 mg Namodenoson groups with a better effect in the higher dose
- Safety - Namodenoson continued to have a safe profile and was very well tolerated with no drug emergent severe adverse effects and no hepatotoxicity

“We were very pleased that the AASLD accepted our late breaking abstract for an oral presentation, a prominent platform through which we shared these important study results with the leading scientists and health care professionals committed to preventing and curing liver diseases. We thank Dr. Safadi for delivering the presentation,” stated Can-Fite CEO Dr. Pnina Fishman.

Dr. Safadi added, “Namodenoson’s very impressive study data may result in a promising drug for the treatment of NAFLD/NASH due to the combination of good efficacy and favorable safety.”

### **About Can-Fite BioPharma Ltd.**

Can-Fite BioPharma Ltd. (NYSE American: 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, liver, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for rheumatoid arthritis/psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint in a Phase II trial 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 HCC 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. These drugs have an excellent safety profile with experience in over 1,500 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, 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. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; the impact of the COVID-19 pandemic; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed 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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