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Can-Fite Reports Positive Top Line Results from its Phase II NASH Study with Namodenoson

- ***Main study endpoints were dose dependent and significantly achieved***
- ***Prof. Safadi, principal investigator: "The study shows Namodenoson has therapeutic effects with a good safety profile and is a very strong candidate for continued clinical development in the treatment of NAFLD/NASH "***

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 and liver diseases, today announced that its Phase II exploratory NAFLD/NASH study with Namodenoson achieved its efficacy endpoints, while continuing to demonstrate a good safety profile.

The Phase II double-blind, placebo-controlled, dose-finding efficacy and safety study enrolled 60 patients with non-alcoholic fatty liver disease (NAFLD) with or without non-alcoholic steatohepatitis (NASH) in three clinical sites in Israel including Hadassah Medical Center, Jerusalem; Rabin Medical Center, Petach Tikva; and Holy Family Hospital, Nazareth; with Prof. Rifaat Safadi as the Principal Investigator. 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. The study's end points included among others alanine aminotransferase (ALT) and aspartate aminotransferase (AST) blood level, % of liver fat, liver stiffness, serum adiponectin, leptin and patient's weight loss.

Therapeutically significant positive data and trends were found as follows:

- ALT and AST - a dose response decrease compared to placebo, indicating a reduction of hepatic inflammation was achieved:
  - % of patients who reached ALT normalization at follow up was 36.8% in the 25 mg dose vs. 10% in the placebo (p=0.038). In the 12.5 mg dose, 23.8% was recorded at follow up.
  - ALT Change from baseline (CFB) and % change from baseline (PCFB) - in the 25 mg group, CFB decreased by 15.4 U/L (p=0.066) and PCFB by 22% (p=0.079) compared to placebo (1.7 U/L, 3.0%, respectively). In the 12.5 mg group, a decrease CFB of 10.4 U/L and PCFB of 8.2% was recorded.
  - AST CFB and PCFB - in the 25 mg group, CFB decreased by 8.1 U/L (p=0.03) and PCFB by 17.9% (p=0.05) compared to placebo (increase of 0.3 U/L, decrease of 1.3%, respectively). In the 12.5 mg group, a decrease in CFB of 7.4 U/L and PCFB of 8.1 % was recorded.
- PCFB of liver fat as measured by PDFF (proton density fat fraction on magnetic resonance imaging) and liver stiffness measured by CAP Fibroscan, showed a trend of decrease in the 25 mg and 12.5 mg groups throughout the study period, reflecting

improvement in both parameters.

- Serum adiponection levels increased in the 25 mg by 220 ng/mL and the 12.5 mg dose group by 539 ng/mL (p=0.03). Adiponectin is a cytokine with robust anti-inflammatory and anti-fibrotic effects that is used as a biomarker in NAFLD/NASH trials.
- Body weight – a linear decrease was recorded in the 25 mg and 12.5 mg groups.
- The blood expression level of the A3 adenosine receptor (A3AR) biomarker was stable, demonstrating the presence of the receptor after chronic treatment and reflecting the validity of the target.
- Namodenoson continued to be safe and very well tolerated with no reported drug emergent severe adverse effects and no reported hepatotoxicity.
- All study parameters above continued to improve through week 16.

Prof. Rifaat Safadi commented, “We are very pleased with the outcome of this study which shows clear efficacy and safety. One of the goals of this study was to determine the optimal dosage, and we have achieved that, as it appears from the data that 25 mg is both safe and most effective. Namodenoson is a very strong candidate for continued clinical development in the treatment of NAFLD/NASH, particularly since no other treatment options are approved for this specific and growing unmet need.”

Can-Fite CEO Dr. Pnina Fishman stated, “The data indicate Namodenoson’s robust anti-NAFLD/NASH effects. We are very pleased that the patients benefitted from treatment and we look forward to advancing this into the next phase of clinical development. ”

The NASH market is estimated to reach $35-40 billion by 2025.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). 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.

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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is 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.

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 recent outbreak of coronavirus; 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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