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Can-Fite Announces Final Data Analysis from Phase II NASH Study: Highly Significant and Sustained Reduction in Liver Fat Volume Throughout Study Period

- ***Results confirm 25 mg Namodenoson as optimal dose based on MRI-PDFF analysis and liver enzymes, reduction of liver fibrosis and resolving all cases of NASH; Namodenoson continues to demonstrate a very good safety profile after drug treatment***
- ***Prof. Rifaat Safadi, study principal investigator: "I am very pleased with these compelling data. The next clinical trial protocol to advance Namodenoson in the treatment of NASH and NAFLD is now being developed"***

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 the final data analysis from its Phase II study of Namodenoson in the treatment of patients with non-alcoholic fatty liver disease (NAFLD) with or without non-alcoholic steatohepatitis (NASH) has been completed. As a whole, the data show that Namodenoson at the 25 mg dose produced statistically significant results in all measures of efficacy, while also having a strong safety profile and well tolerated.

New data resulting from the final analysis included additional results from MRI-PDFF (proton density fat fraction on magnetic resonance imaging) and liver stiffness measured by CAP Fibroscan. An evaluation based on per patient liver volume revealed that liver fat volume decreased in the Namodenoson treated groups vs. the placebo (12.5 mg=81.2; 25 mg =102.1, vs. placebo= 33.0) with a high significance (12.5mg p=0.036; 25mg p=0.027, respectively). The percentage of fat volume decrease was also statistically significant, with the Namodenoson 12.5 mg group declining by 3.68%, and the 25 mg group declining by 4.33% vs. the placebo at 2.61% (25 mg p=0.036). This provides additional support for the anti-steatotic effect of Namodenoson and additional assurance that 25 mg is the more efficacious dose.

- **Anti-Inflammatory Effect**

  Namodenoson significantly reduced two liver enzymes, aspartate aminotransferase (AST) and alanine aminotransferase (ALT), which are elevated in a damaged liver, and increased the anti-inflammatory cytokine adiponectin known also to act as an anti-fibrotic factor. Serum adiponectin levels increased in the 25 mg dose group 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. In addition, a dose response decrease compared to placebo was observed, 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; and

- 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.

- **Reduction of Liver Fibrosis**

Patients treated with 25 mg of Namodenoson had a statistically significant reduction in hepatic fibrosis as measured by the Fibrosis-4 (FIB-4) score, as compared to placebo. FIB-4 change from baseline improved by -0.089 in patients dosed with 25 mg of Namodenoson, as compared to the placebo group which deteriorated from baseline by 0.042 points, with p=0.026. FIB-4 is a non-invasive marker of hepatic fibrosis consisting of four parameters including age, platelet counts, and AST and ALT.

- **Reduction of Liver Steatosis**

In the Namodenoson 25 mg treated group, the proportion of patients with high steatosis scores declined from 37.5% to 13.3% of the population, as compared to the placebo treated group in which the proportion of patients with high steatosis scores decreased from 37.5% to 35.3% of the population, with p=0.08. Steatosis was assessed by Controlled Attenuation Parameter (CAP) measurement of the FibroScan, a non-invasive marker of hepatic steatosis.

- **NASH – All Cases Resolved**

25% of patients randomized into the Namodenoson 25 mg dosed group had NASH at baseline, as compared to none in the placebo group, which comprised of patients who had NAFLD without NASH at baseline. Following 12 weeks of treatment, all NASH cases were resolved in patients treated with 25 mg of Namodenoson, as compared to new NASH that developed in the placebo group representing 5% of that population, with p<0.009. NASH was evaluated by FibroScan-AST (FAST) score, a noninvasive marker of NASH, the severe form of NAFLD (equivalent to biopsy findings of NAS≥4, F≥2), measured by FibroScan elastography, CAP and serum AST.

- **Decrease in Body weight**

A linear decrease in body weight was recorded in the 25 mg and 12.5 mg Namodenoson groups.

- **A3 Adenosine Receptor (A3AR)**

  The A3AR biomarker was stable, demonstrating the presence of the receptor after chronic treatment and reflecting the validity of the target.

- **Safety**

  Namodenoson continued to be safe and very well tolerated with no drug emergent severe adverse effects and no hepatotoxicity.

“We are very pleased with these compelling data. The next clinical trial protocol to advance Namodenoson in the treatment of NASH and NAFLD is now being developed. With the clear need for approved drugs in this indication, I believe distribution partners for Can-Fite will likely take notice of these results,” stated Prof. Rifaat Safadi of Hadassah Medical Center, the Principal Investigator of the study.

The Phase II 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.

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 COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Piclidenoson has been approved for a pilot clinical trial in Israel to treat COVID-19 infected patients with moderate-to-severe symptoms. 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.

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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