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Can-Fite Reports on Progress With Its Namodenoson NASH Program

- *Top NASH U.S. Key Opinion Leaders advise on the design of a Phase IIb protocol*
- *Manufacturing of Namodenoson for the Phase IIb study is completed*
- *NASH patents are now issued in U.S. & Europe*

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 the following progress with its Namodenoson drug candidate for non-alcoholic steatohepatitis (NASH) treatment:

1. The Company is currently engaged in the design of a Phase IIb study for Namodenoson in the treatment of NASH. The protocol is being developed in conjunction with leading Key Opinion Leaders (KOLs) in NASH and liver diseases including Dr. Scott Friedman, Chief of the Division of Liver Diseases at the Icahn School of Medicine at Mount Sinai in New York, and Dr. Stephen A. Harrison, Medical Director of Pinnacle Clinical Research, both of whom were involved in the design of Namodenoson's successfully completed Phase II study in NAFLD/NASH which achieved its efficacy endpoints.
2. Drug supply - Manufacturing of Namodenoson for the upcoming clinical study has been completed.
3. NASH patents were issued by the U.S. & European patent offices. Can-Fite's NASH clinical program is now protected by claims covering the use of the A3 adenosine receptor (A3AR), the target of Can-Fite's platform technology, in reducing ectopic fat accumulation particularly in fatty liver as manifested in nonalcoholic fatty liver disease (NAFLD) and NASH.

Namodenoson for the treatment of NASH is licensed for distribution in Korea and China in deals that include upfront and milestone payments.

"We accumulated very important and encouraging data from our well-designed former Phase II study which successfully met its endpoints with 60 patients and determined the optimal dosage. The Phase IIb NASH protocol will dose patients with 25 mg Namodenoson and will measure several safety and efficacy endpoints including liver biopsy," stated Can-Fite CEO Dr. Pnina Fishman.

NASH is a clear and urgent unmet medical need, as there is currently no U.S. FDA approved treatment for the disease. NAFLD is characterized by excess fat accumulation in the liver. According to a study published in Hepatology, an estimated 17%-33% of the population in the U.S. has NAFLD, while the NIH estimates the incidence of NASH in the U.S. at 2-5% of the population. Incidence is increasing based on rising obesity rates. If untreated, NASH can lead to cirrhosis and liver cancer. By 2025, the addressable pharmaceutical market for NASH is estimated to reach $35-40 billion.

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, liver, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for 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.

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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Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

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