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Can-Fite to Initiate Exploratory Phase 2 Trial with Namodenoson in Pancreatic Cancer Patients

- ***Exploratory, small, open-label study aims to assess potential efficacy of Namodenoson following strong preclinical results in pancreatic cancer***
- ***Namodenoson, now in a pivotal Phase 3 liver cancer study, has completely cleared liver cancer in a patient who remains cancer-free 6 years after starting treatment***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced that it will initiate an open-label Phase 2 exploratory trial to assess the efficacy and safety of Namodenoson in the treatment of patients with pancreatic cancer who have received at least one previous systemic therapy.

Patients will receive Namodenoson at a dose of 25 mg orally, twice daily. Efficacy endpoints will include objective response, progression-free survival, duration of response, disease control (defined as an objective response or stable disease), and overall survival. Safety will be assessed as well. The study will be conducted by Dr. Salomon Stemmer, an oncology key opinion leader and Professor at the Institute of Oncology, Rabin Medical Center, Israel.

Namodenoson is currently under a pivotal Phase 3 study for the treatment of advanced liver cancer and has completely cleared cancer in an advanced liver cancer patient who remains cancer-free 6 years after starting treatment.

“This relatively small exploratory trial is designed as an open-label study, enabling us to assess the potential efficacy of Namodenoson in pancreatic cancer. We’ve seen Namodenoson’s potent anti-cancer effects in treating people with liver cancer and believe that based on recent pre-clinical results, our drug may be equally effective in pancreatic cancer, an indication in need of more effective treatments,” stated Can-Fite CEO Dr. Pnina Fishman.

The highest incidence rates for pancreatic cancer are in Asia, Europe, and North America. According to the American Society of Clinical Oncology (ASCO), in 2020, an estimated 496,000 people were diagnosed with pancreatic cancer globally and an estimated 466,000 died from the disease. The 5-year survival rate for people with pancreatic cancer in the U.S. is 11%. Acumen Research estimates the global pancreatic cancer therapeutics market was valued at approximately $3.6 billion in 2021 and is projected to grow to approximately $6.6 billion by 2030.

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: CANF) 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, and inflammatory disease. The Company's lead drug candidate, Piclidenoson recently reported topline results in a Phase III trial for psoriasis. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH), and enrollment is expected to commence in a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer. 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, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, 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 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; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the “Risk Factors” section of Can-Fite’s Annual Report on Form 20-F filed with the SEC on March 30, 2023 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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