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Can-Fite: FDA Approved Compassionate Use Treatment with Namodenoson in a Pancreatic Cancer Patient

Ramat Gan, Israel, March 18, 2025 (GLOBE NEWSWIRE) -- [Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE: CANF), a biotechnology company developing a pipeline of proprietary small molecule drugs targeting oncological and inflammatory diseases, today announced that it received a single FDA approval for the compassionate use treatment of a U.S. based pancreatic cancer patient with its anti-cancer drug Namodenoson.

Compassionate use is the term used when a physician is requesting for a single patient to gain access to an investigational drug for a serious disease. Such investigational drug has not yet been approved by the FDA.

Pnina Fishman, CSO & Chairperson of Can-Fite BioPharma, commented: "We are pleased to offer this compassionate use program with Namodenoson for eligible patient in the US to address the unmet medical needs for pancreatic cancer. Initiating this program is another milestone achieved for Namodenoson, and concurrently to our ongoing Phase 2a clinical trial, as we remain committed to advancing the availability of our drug."

Namodenoson is currently being evaluated in Liveration™, a pivotal Phase III study for advanced liver cancer that has been approved by both the FDA and the European Medicines Agency (EMA). The drug is currently being tested in Israel in a Phase IIa pancreatic cancer clinical study.

Namodenoson, has been also granted Orphan Drug Designation by the FDA for pancreatic cancer. The designation as an orphan drug will provide, among others, potential for market exclusivity for seven years after approval and several and regulatory advantages.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is currently being evaluated in a pivotal Phase III trial for advanced liver cancer, a Phase IIb trial for the treatment of Metabolic Dysfunction-associated Steatohepatitis (MASH), and in a Phase IIa study in pancreatic cancer. A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential expression may be one of the important factors that 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 and is expected to commence a pivotal Phase III. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in a Phase IIa study in pancreatic 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 1,600 patients in clinical studies to date. For more information please visit: <https://www.canfite.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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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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