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Can-Fite's Drug Namodenoson Approved for Compassionate Use Treatment of Advanced Liver Cancer Patients in Romania

- ***Namodenoson induced a complete response with disappearance of all metastases in a patient who will now continue the treatment under a compassionate use program in Romania***
- ***Can Fite's Phase III pivotal study is open for patient enrolment***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, announced today its liver drug candidate Namodenoson has been approved for compassionate use for the treatment of patients with advanced liver cancer in Romania. Namodenoson was previously approved for compassionate use in Israel, where advanced liver cancer patients have been treated for several years.

In parallel, Can-Fite's pivotal Phase III study in patients with advanced liver cancer (hepatocellular carcinoma), is open for patient enrolment and will recruit patients in Israel, the U.S., and five countries in Europe. This pivotal study received a 'green light' to proceed from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and if successfully concluded, the Company will be in a position to submit the drug for approval with each of the regulatory authorities. Namodenoson has Orphan Drug Status with both the FDA and EMA and Fast Track Status with the FDA. A registration plan has been submitted to and accepted by the FDA.

"We are committed to providing Namodenoson, with an excellent safety profile and strong efficacy in this patient population in clinical trials to date, to fulfill an urgent unmet medical need. The anti-cancer effect of Namodenoson together with its liver protective properties make it unique among anti-cancer drugs for this devastating disease," stated Can-Fite CEO Dr. Pnina Fishman.

The hepatocellular carcinoma (HCC) drug market is expected to reach $3.8 billion in 2027 in the G8 countries according to DelveInsight. The American Cancer Society estimates that in the U.S., liver cancer incidence has tripled since 1980, with an estimated 41,000 cases diagnosed and 31,000 deaths annually. Incidence of liver cancer is much higher in other countries, with more than 800,000 diagnoses and 700,000 deaths estimated globally each year.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is being evaluated as a second line

treatment for advanced hepatocellular carcinoma in a pivotal Phase III trial. The drug is currently in an ongoing Phase II trial 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, 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 24, 2022 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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