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Can-Fite Announces Publication of Namodenoson Liver Cancer Study in Peer Reviewed Journal—Cancers

- ***Significant 12-month overall survival benefit in the CPB7 population and 2 patients are still under treatment for more than 3.5 years***
- ***Namodenoson is headed into a global pivotal Phase III study***

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 a scientific paper titled, “Namodenoson in Advanced Hepatocellular Carcinoma and Child–Pugh B Cirrhosis: Randomized Placebo-Controlled Clinical Trial” was published in the peer reviewed journal *Cancers*.

The paper highlights and analyzes results from Can-Fite’s Phase II study, a randomized placebo-controlled trial to investigate Namodenoson as a 2nd-line treatment for advanced hepatocellular carcinoma (HCC) and moderate hepatic dysfunction, as defined by Child–Pugh B (CPB) scores of 7–9. Even though the trial did not meet its primary endpoint, in patients with a CPB score of 7, Namodenoson was associated with a significant improvement in 12-month overall survival and 2 patients are still under treatment for more than 3.5 years.

A pivotal Phase III study of Namodenoson as a 2nd or 3rd line treatment in HCC CPB7 patients has been designed, and both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have agreed with the protocol. Upon successful results, the trial may lead to concurrent marketing approval in the U.S. and Europe. Namodenoson has been granted Orphan Drug Status by both the FDA and EMA, in addition to Fast Track Status by the FDA. Namodenoson continues to be administered to HCC patients under a compassionate use program in Israel.

“With the publication of this study, we believe we are advancing the body of scientific data needed to bring a treatment to HCC patients with Child-Pugh B7. This subset of patients with advanced disease and borderline liver function have few, if any treatment options. Nearly all other liver cancer studies exclude these patients due to poor prognosis. As detailed in our published paper, Namodenoson significantly prolonged 12-month survival in HCC CPB7 patients in our Phase II study. We are hopeful that if our planned pivotal study produces similar results, Can-Fite will be able to offer a much needed therapy to this population of advanced liver cancer patients,” stated Can-Fite CEO Dr. Pnina Fishman.

Liver cancer is one of the leading causes of cancer deaths globally, with an estimated 854,000 new cases and 810,000 deaths annually. DelveInsight estimates the HCC drug market will reach $3.8 billion in 2027 in the G8 countries.

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 2,000 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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