

# Can-Fite Presents New Data on the Treatment of Advanced Liver Cancer with Namodenoson at the ILCA Conference

- *International Liver Cancer Association (ILCA) is devoted exclusively to liver cancer research*
- *A Phase III study protocol for Namodenoson in the treatment of advanced liver cancer CPB7 patients has been developed and is to be presented to the FDA in an End of Phase II meeting*

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today that the Company's Medical Director, Dr. Michael Silverman, has delivered a presentation titled "The Safety and Efficacy of Namodenoson in the Second Line Treatment of Advanced Hepatocellular Carcinoma (HCC) Patients with Underlying Child-Pugh B (CPB) Liver Cirrhosis: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study" at the International Liver Cancer Association (ILCA) annual conference on September 22, 2019 during the Novel Targets and Prognostic Markers Session. The ILCA's 13<sup>th</sup> Annual Conference took place from September 20 to 22, 2019 in Chicago, Illinois. While the Phase II study did not achieve its primary endpoint of overall survival in the whole population (n=78), superiority in overall survival was found in the largest study subpopulation of patients who were classified Child Pugh B7 (CPB7, n=56) based on severity of the underlying cirrhosis, as compared to the placebo treated group. The Phase III study protocol which has already been designed by the Company will include CPB7 patients and will be presented to the U.S. FDA in a scheduled End of Phase II Meeting.

Highlights from Dr. Silverman's presentation included:

- Median overall survival in the CPB7 population of 6.8 months for those treated with Namodenoson as compared to 4.3 months for those treated with placebo
- A partial response rate of 9% in the Namodenoson group versus 0% in the placebo group
- 1-year survival in the CPB7 population was 44% for the Namodenoson treated group, as compared to 18% for patients dosed with placebo (p=0.028)
- Subgroup analyses using a variety of demographic and baseline disease characteristics, such as sex, performance status, and HCC disease status indicate the overall survival advantage of Namodenoson over placebo persists in the vast majority of the subgroups
- The safety profile of Namodenoson continues to be highly favorable, and adverse events related to Namodenoson were generally mild or moderate and transitory, and did not require dose reduction or drug withdrawal

"These results attest to the robustness of Namodenoson activity in treating liver cancer. We

have designed the Phase III trial to focus on the CPB7 subpopulation, and we look forward to meeting with the FDA soon to present the protocol and move forward with patient recruitment,” stated Dr. Silverman.

The [ILCA](#) is the only international organization devoted exclusively to liver cancer research for experts from all related disciplines. Its mission is to lead a global community of physicians, scientists and allied professionals through education and research with the goal to better prevent and treat liver cancer.

### **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 hepatocellular carcinoma, with a recently completed Phase II trial and planned Phase III trial in this indication. 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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is 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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. These drugs have an excellent safety profile with experience in over 1,000 patients in clinical studies to date. For more information please visit: [www.can-fite.com](http://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 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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