March 26, 2019

Can-Fite Announces Phase II Advanced Liver Cancer Top-Line Results for its Orphan/Fast Track Drug Namodenoson

- *The study did not achieve its primary end point of median overall survival in the whole population of 78 patients, however, superiority in median overall survival was found in the largest study subpopulation of 56 patients and in secondary end points including objective response in the whole population, strongly supporting the progression into Phase III.*
- *Dr. Josep Llovet, a Key Opinion Leader in the field of liver cancer, said: "Considering that patients with advanced HCC and severe liver dysfunction do not have any accepted standard of care, the current data from this Phase II trial suggest a signal of efficacy that supports continuing the development of Namodenoson with a Phase III study in this population."*
- *Dr. Salomon Stemmer, the Israeli principal investigator, added: "Given the evidence of clinical benefit of Namodenoson, I plan on offering it to selected HCC CPB patients with the drug in the compassionate use setting."*

Conference call with management scheduled for today, Tuesday March 26 at 8.30 a.m. Eastern time

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 Phase II advanced liver cancer study did not achieve its primary end point of overall survival in the whole population (n=78). At the same time, superiority in overall survival was found in the largest study subpopulation of CPB7 (n=56) and in secondary end points in the whole population, including objective response measured by CT or MRI. These data strongly support the progression into Phase III.

Advanced liver cancer in patients with underlying cirrhosis is categorized into three subclasses based on the severity of cirrhosis, starting with Child Pugh A (**CPA**), mostly treated with Nexavar® and progressing to Child Pugh B (**CPB**) and Child Pugh C (**CPC**), for which there are no drugs on market with proven efficacy.

In the study, the Company enrolled only patients with CPB stage liver cancer with CBP stage patients being further divided into three categories of increasing severity, namely CPB7, CPB8, and CPB9. These patients already failed first line Nexavar and were treated with Namodenoson (25mg), or placebo, as a second line treatment, twice daily, using a 2:1 randomization. The primary endpoint of the study was defined as the length of time the patients lived after receiving treatment or median overall survival (**OS**). Secondary endpoints included safety, the length of time tumors did not grow after treatment, or progression free survival (**PFS**), the percent of patients whose tumors partially shrank after treatment, or

partial response (**PR**), and the percent of patients who were PR or stable, or disease control rate (**DCR**).

Findings from the study include the following:

1. For the whole population (n=78), median OS was 4.1 months for Namodenoson vs. 4.3 months for placebo (HR: 0.82).
2. Pre-planned subpopulation analysis of the CPB7 patients (n=56), revealed that the Namodenoson treated group (n=34) showed median overall survival of 6.8 months vs 4.3 months in placebo (n=22) [HR: 0.77 (95% CI 0.49-1.40)]. Similarly, for this subgroup of patients, PFS was 3.5 months for the Namodenoson treated group vs 1.9 (HR: 0.87) in the placebo group.
3. Objective response in the whole patient population measured by CT or MRI, demonstrated that 9% treated by Namodenoson achieved PR vs 0% in the placebo group.
4. Consistent with safety results from previously completed clinical trials, Namodenoson was generally well-tolerated, with no treated patients being withdrawn for toxicity and no cases of treatment-related deaths.
5. DCR was 18.0% in the Namodenoson group vs 7.1% in the placebo group (p=0.013) after four months of treatment.
6. 32.0% of patients treated with Namodenoson completed at least 12 months of treatment vs 14.3% who were treated with placebo (p=0.058).
7. As of today, two patients in the Namodenoson group are ongoing after 19 and 28 months of treatment, respectively. These patients will continue to receive Namodenoson.
8. All nine patients with CBP9 cirrhosis, the most severe grade allowed into the trial, were randomly assigned to the Namodenoson treatment group (OS=3.5 months), a fact which has distorted the results in the whole population.

Dr. Llovet, a Founder and Director of the Liver Cancer Program and Full Professor of Medicine at the Mount Sinai School of Medicine, New York University, and Professor of Research-ICREA in the BCLC Group, Liver Unit, IDIBAPS-Hospital Clínic, University of Barcelona, stated, “The global incidence of liver cancer continues to increase and has more than tripled in the United States over the last three decades, and currently there are no recommended systemic treatment options for patients with advanced HCC and severe liver dysfunction (Child Pugh B).” Dr. Llovet added, "Considering that patients with advanced HCC and severe liver dysfunction do not have any accepted standard of care, the current data from this Phase II trial suggest a signal of efficacy that supports continuing the development of Namodenoson with a Phase III study in this population. I will be happy to help with the design of the Phase III and serve as the principal investigator of the trial.”

Dr. Salomon M Stemmer, Institute of Oncology, Davidoff Center, Rabin Medical Center, Petah Tikva/Sackler Faculty of Medicine, Tel Aviv University, Israel and the study principal investigator, added, “Given the evidence of Namodenoson’s clinical benefit, I plan on offering it to selected HCC CPB patients in the compassionate use setting.”

“We are encouraged by the advantage shown by Namodenoson in the CPB7 HCC population, a group for which there are no drugs with proven effectiveness,” stated Pnina

Fishman, Chief Executive Officer of Can-Fite. “Since Namodenoson has a favorable safety profile and shows no evidence of hepatotoxicity, it may possess a unique therapeutic index in this high-need population. Given that Namodenoson has been granted Fast Track status by the FDA, we look forward to engaging regulatory authorities in a dialog at the earliest opportunity.”

An abstract for the late-breaking session has been submitted to The American Society of Clinical Oncology (ASCO) annual meeting, to take place May, 2019 in Chicago, IL, USA.

Conference Call

The Company’s management will host a conference call today at 8:30 a.m. Eastern time to discuss the results of the Phase II advanced liver cancer trial. To participate in the conference call, please dial 877-705-6003 (domestic) or 201-493-6725 (international) or 1 809 406 247 in Israel, five minutes prior to the start of the call and provide the Conference ID: 13689112. Investors may also listen via webcast at: http://public.viavid.com/index.php?id=133770. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 90 days following the call.

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 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, 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.

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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