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Can-Fite To Initiate Phase IIb NASH Study with its Drug Candidate Namodenoson

A prior Phase IIa clinical trial has been successfully concluded and met study end points

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 it has received clearance from the Israeli Ministry of Health to commence a Phase IIb study of its drug candidate Namodenoson in the treatment of NASH. Can-Fite expects to commence enrollment in Q3 2021, ahead of the prior expected start date of Q4 2021. The Company expects to expand the study at additional clinical sites in Europe. A prior Phase IIa clinical trial of Namodenoson in the treatment of NASH met study endpoints showing anti-steatotic, anti-inflammatory, and anti-fibrotic effects.

The Phase IIb trial is a multicenter, randomized, double-blind, placebo-controlled study in subjects with biopsy-confirmed NASH. The primary efficacy objective of the trial is to evaluate the efficacy of Namodenoson as compared to placebo in 140 subjects with NASH, as determined by a histological endpoint. Eligible subjects will be randomly assigned in a 2:1 ratio to oral doses of Namodenoson 25 mg every 12 hours or a matching placebo every 12 hours for 36 weeks.

“We are very pleased to receive the Israeli Ministry of Health’s approval to proceed with our Phase IIb NASH study. Namodenoson has the potential to offer a safe and effective treatment for NASH with the aim of reducing liver transplants and improving quality of life and longevity for patients,” stated Can-Fite CEO Dr. Pnina Fishman.

NASH is a clear and urgent unmet medical need, as there currently is no U.S. approved drug to treat the disease. As of [2016](#), NASH was the leading cause for liver transplants among women and second leading cause for liver transplants overall. NASH is expected to become the leading indication for liver transplants in males as well. The NIH estimates the incidence of NASH in the U.S. at 2-5% of the population. Incidence is increasing based on rising obesity rates. By 2025, the addressable pharmaceutical market for NASH is estimated to reach \$35-40 billion.

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 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, 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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