

April 20, 2021

Can-Fite Initiates Preclinical Studies Required by FDA and EMA for the Registration of its Two Lead Drug Candidates

Piclidenoson in Phase III for Psoriasis & Namodenoson to Enter Pivotal Phase III for Liver Cancer

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 and liver diseases, announced today that in preparation for anticipated potential marketing registration filings for its drug candidates Piclidenoson and Namodenoson in the U.S. and Europe, the Company has initiated a series of preclinical studies required by regulators.

As part of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), both regulators require certain preclinical data be submitted along with the pivotal Phase III data.

Piclidenoson is now being evaluated in the COMFORT Phase III clinical study which continues to enroll patients following a positive interim data analysis. The COMFORT study is designed to establish Piclidenoson's superiority as compared to placebo and non-inferiority compared to Otezla® in patients with moderate-to-severe plaque psoriasis.

A pivotal Phase III study of Namodenoson in the treatment of hepatocellular cancer (HCC), the most common form of liver cancer, is expected to commence in the fourth quarter of 2021. Namodenoson has Orphan Drug Status in the U.S. and Europe and Fast Track Status with the FDA. Can-Fite has reached agreement with both the FDA and EMA on the study design and upon successful results, the trial may lead to concurrent marketing approval in the U.S. and Europe.

"Having commenced these important preclinical studies for our lead indications in anticipation of potential NDA and MAA filings, we are eager to bring our drug candidates to market for the benefit of patients in need," stated Can-Fite CEO Dr. Pnina Fishman.

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 COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. 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 recent outbreak of coronavirus; 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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Source: Can-Fite BioPharma Ltd.