

Can-Fite Concludes Successful Meeting with European Medicines Agency (EMA) Regarding Phase III Trial and Registration Plan for Namodenoson in the Treatment of Liver Cancer

Following meetings with both the U.S. FDA and EMA, Can-Fite is ready to submit its protocol and conduct one pivotal trial for registration in both markets

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 successfully concluded a meeting with the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) regarding Phase III development of its drug candidate Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

Namodenoson is Can-Fite's adenosine A3 receptor (A3AR) agonist which has recently been shown to prolong median overall survival (OS) in a selected patient population with HCC in a Phase II clinical trial. Can-Fite sought scientific advice from the EMA to complement previous input from the U.S. Food and Drug Administration (FDA) in its recent End-of-Phase II meeting regarding plans for a Phase III registration trial of Namodenoson in patients with HCC and Child Pugh Class B7 (CPB7) cirrhosis. Having completed its meeting with the SAWP, Can-Fite now has sufficient regulatory input to conduct a registration trial in accordance with the requirements of both the U.S. and the European Union.

The planned trial, a randomized, double blind, placebo controlled trial, will enroll approximately 450 patients with HCC and underlying CPB7 cirrhosis at multiple centers worldwide. Patients will be randomized to oral treatment with either Namodenoson 25 mg or matching placebo given twice daily. The primary efficacy endpoint of the trial is overall survival (OS), based on the favorable OS response seen in the Phase II trial in patients with HCC and CPB7 cirrhosis. Other oncology trial efficacy outcomes, such as tumor radiographic response rates and median progression-free survival, as well as standard safety parameters, will be assessed.

"We appreciate the EMA's advice which, combined with the input we received last October from the U.S. FDA along with recommendations from our academic key opinion leaders, gives us excellent guidance for conducting a successful Phase III clinical and registration program," stated Can-Fite CEO Dr. Pnina Fishman.

According to the American Cancer Society, liver cancer accounts for more than [700,000](#) deaths globally each year. HCC is commonly aggressive with poor survival rates. As new drugs that effectively and safely treat HCC are developed and approved, the market for HCC

treatments is estimated by Delveinsight to reach \$3.8 billion by 2027 for 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 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 recently concluded a Phase II trial which successfully achieved efficacy and safety endpoints in the 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 COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Piclidenoson has been approved for a pilot clinical trial in Israel to treat COVID-19 infected patients with moderate-to-severe symptoms. Can-Fite's liver drug, Namodenoson, is heading 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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