February 13, 2020

Can-Fite Submits Liver Cancer Phase III Protocol and Registration Plan to EMA for Namodenoson

- Can-Fite successfully concluded its End-of-Phase II meeting with the U.S. FDA recently

- One Phase III trial for concurrent regulatory approval in U.S. and Europe upon successful study results

- Namodenoson has Orphan Drug and Fast Track status, addressing projected $3.8 B market

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 inflammatory, cancer and liver diseases, announced today it has submitted the study's protocol design and registration plan for its pivotal Phase III liver cancer trial to the European Medicines Agency's (EMA) Committee for Medicinal Product and Human Use (CHMP). The Phase III pivotal trial will evaluate the efficacy of its drug candidate Namodenoson in patients with advanced hepatocellular carcinoma (HCC), with underlying Child Pugh B7 (CPB7) cirrhosis, whose cancer has progressed on first line therapy

The filing with the EMA follows Can-Fite's successful conclusion of its End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA), in which the FDA agreed with Can-Fite's proposed pivotal Phase III trial design to support a New Drug Application (NDA) submission and approval of Namodenoson in the treatment of HCC.

"Having submitted our study design to both U.S. and European regulators, we look forward to initiating this Phase III study. Should Namodenoson meet the study's primary endpoint of improved overall survival for liver cancer patients, then we intend to file for concurrent approval of our drug in both the U.S. and Europe, two of the largest healthcare markets in the world," stated Can-Fite CEO Dr. Pnina Fishman.

DelveInsight estimates the HCC drug market will reach $3.8 billion in 2027 in the G8 countries. According to the American Cancer Society, in the U.S. liver cancer incidence has tripled since 1980, with an estimated 42,000 cases diagnosed and 32,000 deaths annually. Incidence of liver cancer is much higher in other countries, with more than 800,000 diagnoses and 700,000 deaths estimated globally each year.

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.

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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Source: Can-Fite BioPharma Ltd.