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Can-Fite Updates on its Advanced Liver Cancer Pivotal Phase 3 Study

Namodenoson granted Orphan Drug and Fast track status from the FDA

RAMAT GAN, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced an update on the status of its oncological lead drug candidate, Namodenoson in the treatment of advanced liver cancer. The Phase 3 pivotal study now has 31 recruiting medical centers in Europe, Israel and the US. Namodenoson has Orphan Drug status with both the U.S. Food and Drug Administration (FDA) and European Medicines Agency, as well as Fast Track Status with the FDA. A compassionate use program has also been ongoing in Israel and Romania.

In the former Phase 2 study, conducted in patients with advanced liver cancer, Namodenoson prolonged survival, patients had good quality of life, and in two patients, clearance of peritoneal carcinomas have been reported. In addition, one patient had a long term complete response of more than 7 years.

Liver cancer designated as hepatocellular carcinoma (HCC), is a major global health problem due to its incidence, associated mortality, and lack of effective treatment modalities, particularly for patients with advanced hepatic dysfunction known as disease stage Child Pugh B. 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. The market for HCC treatments is estimated by Delveinsight to reach $3.8 billion by 2027 for the G8 countries.

The current double blind, placebo-controlled trial, known as LIVERATION, will enroll 450 patients diagnosed with advanced liver cancer (hepato-cellular carcinoma) and underlying Child Pugh B7 (CPB7) cirrhosis. Patients will be randomized to oral treatment with either 25 mg of Namodenoson or a matching placebo, in a ratio of 2:1 given twice daily as a second- or third-line treatment. The primary efficacy endpoint of the trial is overall survival. Other oncology trial efficacy outcomes, such as tumor radiographic response rates and median progression-free survival, as well as standard safety parameters, will also be assessed. An interim analysis will be conducted by an Independent Data Monitoring Committee (IDMC) after 50% of enrolled patients are treated.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was 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: CANF) 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, and inflammatory disease. The Company's lead drug candidate, Piclidenoson recently reported topline results in a Phase III trial for psoriasis and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of Metabolic Dysfunction-associated Steatohepatitis (MASH), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic cancer. 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 1,600 patients in clinical studies to date. For more information please visit: www.canfite.com.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, 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; risks related to any resurgence of the COVID-19

pandemic and the war between Israel and Hamas; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the “Risk Factors” section of Can-Fite’s Annual Report on Form 20-F filed with the SEC on March 28, 2024 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

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