Can-Fite Enters Into Collaboration Agreement to Explore Namodenoson's Anti-NASH Effect With Icahn School of Medicine at Mount Sinai in NYC

Can-Fite to Support Research Directed by Scott Friedman, M.D. on Namodenoson in Human Liver Cells

PETACH TIKVA, Israel--(BUSINESS WIRE)-- <u>Can-Fite BioPharma Ltd</u>. (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced a collaborative research agreement with the Icahn School of Medicine at Mount Sinai in New York City. The agreement will support research directed by Scott Friedman, M.D., Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases at the Icahn School of Medicine. The research is aimed at transcriptomic and molecular analyses to further explore the mechanisms of action of Namodenoson (CF102) in human hepatic stellate cells in order to clarify its effect on fibrogenesis that occurs in non-alcoholic steatohepatitis (NASH).

"We are privileged to work with Dr. Friedman, a Key Opinion Leader in the arena of nonalcoholic fatty liver disease (NAFLD) and NASH, to further study and advance our understanding of the molecular mechanism of action of Namodenoson," said Pnina Fishman, Ph.D., Founder and Chief Executive Officer of Can-Fite. "This work aims to provide a more solid foundation for our ongoing efforts to understand the potential of Namodenoson in these therapeutic areas."

In the transcriptomic bioinformatics analysis, Dr. Friedman will research differentially expressed genes and modulated molecular pathways in the transcriptome datasets in association with the experimental perturbations. Integrative (cross-species) analysis with clinical datasets for assessment of association with clinical disease phenotypes and outcomes will be performed. An emphasis will be given to the analysis of the PI3K and the Wnt/ β -catenin pathways, which are up-regulated in NAFLD/NASH livers and found to be improved upon treatment with Namodenoson.

Recent preclinical studies with Namodenoson in collaboration with Rifaat Safadi, M.D., the Head of the Liver Unit, Gastroenterology and Liver Diseases, Division of Medicine at Hadassah Medical Center in Israel, showed an improvement in three cardinal NASH parameters including steatosis, inflammation and fibrosis.

Can-Fite is currently enrolling patients in a Phase II study of Namodenoson in NAFLD/NASH. Based on the recent preclinical data, the primary endpoint of the Phase II study is Percent Change From Baseline (PCFB) in serum alanine aminotransferase (ALT) levels at Week 12 for each dose of CF102 compared to placebo, with the major secondary endpoint being percentage of liver fat as measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF).

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 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: 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, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and 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 forwardlooking statements include, but are not limited to: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181210005169/en/

Can-Fite BioPharma Motti Farbstein <u>info@canfite.com</u> +972-3-9241114 or Media: DGI Comm Laura Radocaj <u>Iradocaj@dgicomm.com</u>

Source: Can-Fite BioPharma Ltd.