Can-Fite Enters into Collaborative Research Agreement with Hadassah Medical Center to Further Explore Namodenoson Mechanism of Action in NASH

- Namodenoson improves steatosis, inflammation and ballooning in pre-clinical studies
- A Phase II study of Namodenoson is enrolling NAFLD/NASH patients

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, today announced the entry into a collaborative research agreement with Hadassah Medical School. This agreement will support research directed by Rifaat Safadi, M.D. aimed at further elucidating the Namodenoson mechanism of action in experimental models of non-alcoholic steatohepatitis (NASH) which represent the human disease.



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Recent pre-clinical studies with Namodenoson showed an improvement in three cardinal NASH parameters including steatosis. inflammation and ballooning, which collectively define the histopathologic NAS (non-alcoholic fatty liver disease [NAFLD] Activity Score). The data. summarized in the accompanying

Data demonstrate a significant anti-NASH effect and represent the basis for Can-Fite's collaborative research program with Dr. Safadi. (Graphic: Business Wire)

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Dr. Safadi is the Head of the Liver Unit, Gastroenterology and Liver Diseases, Division of

Medicine at Hadassah Medical Center and Professor of Internal Medicine, Bowel, Liver Disease, and Metabolic Syndrome at Hadassah University in Israel. He is a prolific researcher and a highly respected thought leader in the field of NASH. Dr. Safadi's areas of expertise include liver and bowel diseases, and the metabolic syndrome. He has published widely in high-impact journals and is also a member of Can-Fite's Clinical Advisory Board.

"Can-Fite's Namodenoson drug is unique among today's NASH drugs under development due to its excellent safety profile and the positive effect on steatosis, inflammation and fibrosis. We are very happy to initiate this collaboration," said Dr. Safadi.

Lately Can-Fite initiated patient enrollment for a Phase II study with Namodenoson in NAFLD/NASH patients with evidence of active inflammation. Based on the recent pre-clinical data, the company has changed the primary end point of the Phase II study to the antiinflammatory effect of the drug, as determined by blood ALT levels, and changed the major secondary end point to % of liver fat, measured by PDFF (proton density fat fraction). The Company believes this amendment sets the stage to increase the chances of trial success by aligning the clinical outcomes with the drug's mechanism of action.

"We are privileged to work with Dr. Safadi to further study and advance the drug's mechanism of action," said Pnina Fishman, Ph.D., Founder and Chief Executive Officer of Can-Fite.

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 multibillion-dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis in early 2018. 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 nonalcoholic 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.

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