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Can-Fite Announces Preparation for End-of-Phase II Meeting with FDA to Initiate the Phase III Liver Cancer Study for Namodenoson

Fast Track and Orphan Drug Status; No treatment currently exists for advanced liver cancer patients in whom the current standard of care does not work

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PETACH TIKVA, Israel--(BUSINESS WIRE)--Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today it is conducting preparatory work for a planned pivotal Phase III study of its drug candidate Namodenoson in the treatment of advanced liver cancer in patients as a first line and second line treatment. The Company recently announced results from its Phase II study of Namodenoson in the treatment of advanced liver cancer. Namodenoson was found to increase overall survival in hepatocellular carcinoma (HCC) patients with Child Pugh B7, the largest subpopulation of the study, as compared to placebo, even though the trial did not meet its primary endpoint.

An end of Phase II meeting with the U.S. Food and Drug Administration to review study data and to present the design of the Phase III clinical trial is expected soon. The FDA has granted Namodenoson both Orphan Drug and Fast Track status providing a pathway for accelerated approval based on unmet need in the treatment of advanced liver cancer. Fast Track designation offers advantages including more frequent meetings with the FDA and rolling review, which provides the opportunity to submit parts of its New Drug Application (NDA) for review prior to completing the entire application for commercialization. Orphan Drug designation includes 7-year market exclusivity following marketing approval, FDA assistance during the drug development process, and exemption of application fees.

Key Opinion Leader in liver cancer, Dr. Josep Llovet is slated to be the Principal Investigator of the planned Phase III trial and is currently working closely with Can-Fite on the study's protocol and design. Dr. Llovet is the Director of the Liver Cancer Program and Full Professor of Medicine at the Mount Sinai School of Medicine, New York University, and Professor of Research-ICREA Liver Unit, IDIBAPS-Hospital Clinic, University of Barcelona.

Dr. Llovet commented, "Today, patients with advanced liver cancerand severe liver dysfunction do not have any accepted standard of care that is effective. Based on Namodenoson's signal of efficacy in the recently completed Phase II trial, a Phase III study in the population of patients with HCC Child Pugh B7 is warranted and I am pleased to help with the design of the Phase III study and to serve as the Principal Investigator of the trial."

Can-Fite has engaged the services of a clinical research organization (CRO), the Weinberg

Group, based in Washington DC to help with the preparation of all materials for the FDA meeting.

“We look forward to our upcoming meeting with the FDA regarding our Phase III study design. We are hopeful that based on efficacy data in the largest subgroup of the patient population from our Phase II study, we can move forward into a pivotal Phase III trial for marketing approval with the guidance of the FDA,” stated Can-Fite CEO Pnina Fishman.”

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, 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,

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