Can-Fite’s Phase II NAFLD/NASH Trial with Namodenoson Set to Commence Patient Enrollment Following Conclusion of Successful Clinical Investigator Meeting

Compelling unmet need for NAFLD/NASH drug to address estimated $35 billion treatment market by 2025

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today that it successfully concluded a Clinical Investigator Meeting with the principal investigators, researchers, and doctors participating as clinical investigators in the Company’s Phase II trial of its drug candidate Namodenoson in the treatment of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

“We conducted a successful Investigator Meeting with clinical researchers eager to evaluate Namodenoson in the treatment of NAFLD/NASH. Details of the Phase II clinical trial protocol were reviewed and questions and comments from clinicians were addressed. We are pleased to have some of the most prestigious medical institutions including Hadassah Medical Center and Rabin Medical Center serve as clinical sites for the trial,” stated Can-Fite Medical Director Dr. Michael Silverman. “We anticipate patient enrollment to commence this quarter.”

The Phase II multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of Namodenoson in the treatment of NAFLD/NASH will enroll approximately 60 patients with NAFLD, with or without NASH. Patients will be enrolled in three arms, including two different dosages of Namodenoson and a placebo, given via oral tablets twice daily. The study's primary endpoints will be percent change from baseline in liver triglyceride (fat) concentration measured by nuclear magnetic resonance spectroscopy (NMRS) and safety.

The Phase II trial design is based on preclinical studies showing Namodenoson's efficacy in reducing liver fat in NASH models as compared to placebo, improving liver function, and regenerating liver cells. Can-Fite’s estimated cost of the Phase II trial is under $1 million. Namodenoson supplies are ready to be administered and the costs of supply have been paid.
By 2025, the addressable pharmaceutical market for NASH is estimated to reach $35-40 billion.

About NAFLD/NASH

NAFLD is characterized by excess fat accumulation in the form of triglycerides (steatosis) in the liver. According to a study published in Hepatology, an estimated 17%-33% of the population in the U.S. has NAFLD, with a higher prevalence in people with type II diabetes. Incidence is increasing based on rising obesity rates. NAFLD includes a range of liver diseases, with NASH being the more advanced form, manifesting as hepatic injury and inflammation. According to the NIH, the incidence of NASH in the U.S. is believed to affect 2-5% of the population. The spectrum of NAFLDs resembles alcoholic liver disease; however, they occur in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer. By 2025, the addressable pharmaceutical market for NASH is estimated to reach $35-40 billion.

About Namodenoson (CF102)

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. Can-Fite has received Orphan Drug Designation for Namodenoson in Europe and the U.S., as well as Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: 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 scheduled to enter Phase III trials in 2017 for two indications, rheumatoid arthritis and psoriasis. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug Namodenoson is in Phase II trials for patients with liver cancer and is slated to enter Phase II 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 hepatocellular carcinoma 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 is being prepared for an IND submission to the FDA and a Phase I trial. 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: 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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