

March 17, 2016

Can-Fite Submits Phase III Protocol Design and Registration Plan to European Medicines Agency (EMA) for CF101 in the Treatment of Rheumatoid Arthritis

Trial expected to commence in Q2/3 of 2016

PETACH TIKVA, Israel, March 17, 2016 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, today announced it has submitted to the European Medicines Agency (EMA) a protocol design for its Phase III trial and Registration Plan for the Company's lead compound CF101 in the treatment of rheumatoid arthritis following a pre-submission meeting with the EMA. The global trial is expected to commence in either the second or third quarter of 2016.

The planned Phase III trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study that will investigate the efficacy and safety of CF101 administered orally twice daily for 16 weeks to patients with active rheumatoid arthritis treated with conventional disease modifying drugs. The study will have three arms, a 1 mg CF101 dose, a 2 mg CF101 dose and placebo, given orally twice daily in the form of tablets. The study is expected to enroll 360 patients and the primary endpoint is expected to be low disease activity. Inclusion criteria will include patients who have high expression of the A3 adenosine receptor (A3AR), a biomarker that has been shown by the company to identify patients who will respond to CF101. A3AR and its correlation to patients' response to the drug will be analyzed upon study conclusion. Based on Can-Fite's Phase II clinical studies with CF101 in patients with active rheumatoid arthritis, the percentage of patients with high expression of A3AR is estimated to be approximately 70%.

"Submission of this Phase III protocol design to the EMA in the first quarter of 2016 was an important milestone and we look forward to commencing our trial, upon the European regulator's approval of our protocol. We plan to conduct the study in several European countries, Canada, U.S. and Israel. We were very pleased to be in a position to submit our Registration Plan for CF101, to the EMA, which we believe will give us greater visibility on our path to approval," stated Can-Fite CEO Dr. Pnina Fishman.

Rheumatoid arthritis is a chronic, systematic, autoimmune inflammatory disease that manifests as joint pain, stiffness, and swelling. According to Visiongain, the global rheumatoid arthritis market is forecasted to reach \$38.5 billion by 2017.

About CF101

CF101 is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical

studies. CF101 is currently under development for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis (completed Phase II) and psoriasis (completed Phase II/III).

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 CF101 drug candidate is scheduled to enter Phase III trials in 2016 for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug CF102 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). CF102 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. CF102 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 1,200 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, 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, including, but not limited to, the factors summarized 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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