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Can-Fite Completes the Design of the Rheumatoid Arthritis Phase III Study of Its Lead Drug Candidate CF101

The estimated global market of Rheumatoid Arthritis is expected to reach \$38B in 2017

PETACH TIKVA, Israel, Dec. 30, 2014 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT:CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, announced today that it completed the design of the Rheumatoid Arthritis (RA) Phase III study of its lead drug candidate CF101. Dr. M. Silverman, Can-Fite Medical Director, and Dr. Lee Simon, a key opinion leader in the field of autoimmune inflammatory diseases, designed the Phase III clinical study.

The Phase III study will be a multicenter, randomized, double-blind, placebo-controlled, parallel-group study that will investigate the efficacy and safety of daily CF101 administered orally as a monotherapy for 12 weeks to patients with active RA. The study will have three arms, a 2 mg CF101 dose, a 3mg CF101 dose and placebo, given orally twice daily in the form of tablets. Approximately 300 patients are expected to be enrolled in the study, where sample size for each treatment group will be approximately 100 patients and will provide a statistical power of at least 90%. The study primary end point will be ACR 20 response at Week 12. The A3 adenosine receptor biomarker will be evaluated prior to treatment and its correlation to patients' response to the drug will be analyzed upon study conclusion.

The Phase III design is based on positive data received from the company's completed Phase IIb study in which CF101 was administered as a monotherapy. The Phase IIb study was a 12-week multicenter, randomized, double-blind, placebo-controlled, parallel-group study involving 79 patients with active RA. In the study, patients treated with 1mg CF101 met all primary efficacy endpoints with statistically significant superiority over placebo in reducing signs and symptoms of RA as compared to the placebo.

Can-Fite CEO Pnina Fishman stated, "We are very pleased that the Phase III design is completed and based on the positive data of the prior Phase II study we believe that increasing the drug dose will yield positive data and those patients with RA will be able to benefit from our oral drug."

According to independent business information provider [visiongain](#), the global RA drug market is expected to generate revenues of \$38.5bn in 2017. Can-Fite's Phase II/III psoriasis trial is ongoing with data expected to be released in the first quarter of 2015.

[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 and inflammatory diseases. The Company's CF101 is in Phase II/III trials for the treatment of psoriasis and the Company is preparing for a Phase III CF101 trial for rheumatoid arthritis. Can-Fite's liver cancer drug CF102 is commencing Phase II trials and has been granted Orphan Drug Designation 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. 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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