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Can-Fite Reports Top-Line Results from Phase II/III Trial for CF101 in Treatment of Psoriasis

The Study did not achieve its primary efficacy endpoint

PETACH TIKVA, Israel, March 30, 2015 /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 its Phase II/III psoriasis trial for the Company's drug candidate CF101 did not achieve its primary endpoint.

This Phase II/III double-blind, placebo-controlled study was designed to test the efficacy of CF101 in patients with moderate-to-severe plaque psoriasis. Can-Fite enrolled a total of 326 patients through 17 clinical centers in the U.S., Europe, and Israel. The first study segment was comprised of three arms with 103 patients who received either 1 mg of CF101; 2 mg of CF101; or placebo. All patients receiving placebo were switched to either 1 mg or 2 mg of CF101 after 12 weeks and continued receiving treatment until week 24. Following a positive interim analysis, Can-Fite continued to enroll patients to the second segment of the study. The second study segment was comprised of two arms with 223 patients receiving either 2 mg of CF101 or placebo. All patients receiving placebo were switched to 2 mg of CF101 after 16 weeks and continued receiving treatment until week 32. The primary efficacy endpoint was a statistically significant improvement in the Psoriasis Area Sensitivity Index (PASI) score relative to placebo treatment, and the secondary endpoints were, among others, the Physicians' Global Assessment (PGA) score as well as various safety parameters.

The proportion of patients treated with CF101 who achieved at least a 75% improvement from baseline in disease severity at week 12, as measured by PASI 75 was 8.5% vs. 6.9% in the placebo group. With respect to PGA, 6.4% of patients treated with CF101 achieved clear or almost clear skin at week 12 compared to 3.4% of the placebo patients. CF101 was found to be safe and well tolerated.

"We are disappointed that our trial did not meet its primary endpoint. Regrettably, in the PASI 75 and PGA we did not see any real effect in patients over placebo. We have not yet completed our analysis of secondary endpoint and sub-group analysis and intend to complete it in the near future. Can-Fite is continuing its research and development efforts in relation to its drugs and indications in the pipeline." stated Can-Fite CEO Dr. Pnina Fishman.

About Psoriasis

Psoriasis is a skin condition that affects 2% to 3% of the general population according to the [National Psoriasis Foundation](#). The disease is manifested by scaly plaques on the skin and in the severe form has a major effect on the physical and emotional well-being of the

patients. Topical agents are typically used for mild disease, phototherapy for moderate disease, and systemic agents for severe disease. For moderate to severe cases, systemic biologic drugs, delivered via IV, have dominated the market. According to the National Psoriasis Foundation, common side effects of biologics include respiratory infections, flu-like symptoms, and injection site reactions while rare side effects include serious nervous system disorders, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes, blood disorders, and certain types of cancer. We believe a significant need remains for novel oral and safe drugs for patients who do not respond to existing therapies or for whom these therapies are unsuitable.

About CF101

CF101, an A3 adenosine receptor agonist, is a novel, first in class, small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical studies. CF101 is currently developed for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis (completed Phase II) and psoriasis (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 recently completed its 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 in 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. The Company's CF602 has shown efficacy in the treatment of erectile dysfunction. Can-Fite has initiated a full pre-clinical program for CF602 in preparation for filing an IND with the U.S. FDA in this indication. 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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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/can-fite-reports-top-line-results-from-phase-iiiii-trial-for-cf101-in-treatment-of-psoriasis-300057529.html>

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