

Can-Fite BioPharma Announces Top-Line Results of Phase IIb Study with CF101 as a Monotherapy for Rheumatoid Arthritis

PETACH TIKVA, Israel, Dec. 23, 2013 /PRNewswire/ -- [Can-Fite BioPharma](#) Ltd. (TASE: CFBI), (NYSE MKT: CANF), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, announced results from a 12-week, placebo-controlled Phase IIb study involving 79 patients with active rheumatoid arthritis ("RA") for its proprietary drug CF101, an A3 adenosine receptor ("A3AR") agonist. The study entailed 2 arms, a placebo and a CF101 1 mg treated group, in which CF101 was administered orally twice-daily as a monotherapy for 12 weeks to patients with RA. Only patients with elevated baseline expression levels of the biomarker A3AR were enrolled in the study.

In the study, CF101 1 mg met all primary efficacy endpoints, showing statistically significant superiority over placebo in reducing signs and symptoms of RA as compared to the placebo, as measured by ACR20 response rates at 12 weeks (ACR20 response rates: placebo = 25%; CF101 = 49%, $p=0.035$). This advantage was also evident in higher response rates in the CF101 group versus placebo in ACR50 (ACR50 response rates: placebo = 9%; CF101 = 19%) and ACR70 (ACR70 response rates: placebo = 3% ; CF101 = 11%). Similar to the Company's observations in the previously reported CF101 psoriasis trials, the response of patients with RA was cumulative over time, suggesting a consistent anti-inflammatory effect of CF101. Moreover, half of the RA patients treated with CF101 showed clinically meaningful improvement.

CF101 was very well-tolerated with no evidence of immunosuppression. CF101 had an excellent safety profile, as has already been shown in more than 750 patients in previously reported Phase II clinical studies in autoimmune and inflammatory diseases. Additionally, all treatment-emergent adverse events were mild to moderate in intensity.

These results will be presented at the 9th International Congress on Autoimmunity in Nice, France from March 26-30, 2014.

"Along with our recently presented interim analysis data with CF101 in psoriasis, results from this study in RA, in which half of the patients treated with CF101 showed clinically meaningful improvement, demonstrate the potential of the A3AR agonist CF101 in inflammatory indications. The data also supports the notion that A3AR can be used as a biological predictive marker," stated Prina Fishman, Chief Executive Officer of Can-Fite.

About CF101

CF101 is a small molecule orally bioavailable drug which binds with high affinity and selectivity to the A3AR, which is known to be over-expressed in inflammatory cells. The correlation between A3AR expression levels prior to treatment and patients' response to CF101 suggests that the A3AR may be utilized a predictive biomarker to be analyzed prior to patients' treatment. CF101 is currently being developed for the treatment of RA and other

inflammatory indications, including psoriasis, for which positive data from an interim analysis of an ongoing Phase II/III study was recently released by the Company.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd is an Israeli public company, the ordinary shares of which are traded on the Tel Aviv Stock Exchange (the "TASE") (TASE: CFBI). Level II American Depositary Receipts of the Company currently trade on the NYSE MKT (NYSE MKT: CANF). Can-Fite, which commenced business activity in 2000, was founded by Pnina Fishman, Ph.D., researcher in the Rabin Medical Center, and Ilan Cohn Ph.D., patent attorney and senior partner at Reinhold Cohn Patent Attorneys in Israel. Dr. Fishman serves as the Chief Executive Officer of Can-Fite. Dr. Fishman founded Can-Fite on the basis of her scientific findings, and Can-Fite is focused on the development of small molecule orally bioavailable drugs, in particular, ligands that bind to the A3 adenosine receptor. Such drugs mediate anti-inflammatory and anti-cancer effects and the A3AR is developed as a biological predictive marker. Can-Fite's lead drug candidate, CF101, is in clinical development for the treatment of autoimmune inflammatory diseases including Rheumatoid Arthritis and Psoriasis. Can-Fite's CF102 drug candidate is being developed for the treatment of liver diseases and CF602 is being developed for the treatment of inflammation and sexual dysfunction. To date, more than 700 patients have participated in clinical trials conducted by Can-Fite. Can-Fite previously spun off its activity in the ophthalmic field to Ophthalix Inc., in which it holds 82%, and is currently listed on the U.S. Over-the-Counter Markets (OTCQB: OPLI).

Forward-Looking Statements

This press release contains 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 (the "SEC"), 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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