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OphthaliX to Retrospectively Analyze Phase III Dry Eye Syndrome Study Data Based on A3 Adenosine Receptor Biomarker

Following the Successful Utilization of A3 Adenosine Receptor Biomarker in Can-Fite's Phase IIb Rheumatoid Arthritis Study

PETACH TIKVA, Israel, Dec. 31, 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 today the following:

The Company's subsidiary, OphthaliX Inc. (OTCQB: OPLI), will conduct a retrospective analysis of its Phase III Dry Eye Syndrome study data to determine if there is a correlation between the A3 adenosine receptor ("A3AR") biomarker and patients' response to CF101. This analysis will be conducted as a result of recent positive data from the Phase IIb Rheumatoid Arthritis study where patients have been enrolled based on the presence of this biomarker.

In order to perform the retrospective analysis, blood samples will be collected from patients who participated in the Phase III Dry Eye Syndrome study and analyzed for the expression of the biomarker.

As previously announced, Can-Fite was recently granted a U.S. patent for the utilization of the A3AR as a biomarker to predict patients' response to CF101 in autoimmune inflammatory indications.

Can-Fite's platform technology is based on the development of small molecule orally bioavailable drugs, in particular, ligands that bind to the A3AR, which is known to be over-expressed in inflammatory cells. The correlation between A3AR expression levels prior to treatment with CF101 and patients' response to the drug suggest that the A3AR may be a predictive biomarker to be analyzed prior to CF101 treatment. As such, and based on past Phase IIa clinical data in Rheumatoid Arthritis patients suggesting a direct, statistically significant correlation, Can-Fite developed a simple blood assay to test the expression level of such a biomarker, which is the subject of the patent. Most currently, all potential patients for Can-Fite's Phase IIb clinical trial in Rheumatoid Arthritis were tested for such A3AR biomarker prior to treatment and only those with an A3AR over-expression were enrolled in the trial.

"Following the successful data from our recent Phase IIb Rheumatoid Arthritis study where the utilization of the specific biomarker has been validated, we decided to retrospectively analyze its presence in the patient population of the Phase III Dry Eye Syndrome study to

better understand the potential of CF101 for this indication." stated Pnina 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 Rheumatoid Arthritis 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 Depository 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 it's 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.

Contact

IRTH Communications
Robert Haag
canf@IRTHCommunications.com
1-866-976-4784

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