

# OphthaliX Announces Top-Line Results of Phase III Study with CF101 for Dry Eye Syndrome

Written by Australian Business

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PETACH TIKVA, Israel, Dec. 30, 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 that its subsidiary **Ophth**

## **aliX Inc. (OTCBB:OPLI)**

released results from a 24 week, placebo-controlled phase III study involving 237 patients with moderate-to-severe Dry Eye Syndrome who were treated with its licensed drug CF101, an A3 adenosine receptor agonist. The patients were randomized to receive two oral doses of CF101 (0.1 mg or 1.0 mg) or a placebo, for a period of 24 weeks.

In the study, CF101 did not meet the primary efficacy endpoint of complete clearing of corneal staining, nor the secondary efficacy endpoints. Nonetheless, CF101 was found to be well tolerated.

CF101 is developed by Can-Fite for anti-inflammatory indications. Last week, Can-Fite announced positive data from a Phase II clinical trial in Rheumatoid Arthritis. In addition, Can-Fite is conducting a phase II/III clinical study in patients with Psoriasis. Can-Fite announced positive interim analysis of the Psoriasis study several months ago and patients enrollment in the second segment is ongoing in the United States, Europe and Israel. The final data from this study is expected to be released during 2014.

Global Data estimates that the global market for rheumatoid arthritis therapeutics was \$12 billion in 2010 and is projected to reach \$18 billion by 2020. The global market for treating psoriasis was \$3.3 billion in 2010 and is projected to reach \$6.7 billion

by 2018, according to Global Data.

OphthaliX is also developing CF101 for the treatment of Glaucoma and Uveitis. The interim data from the ongoing phase II study in Glaucoma is expected to be released during 2014.

Can-Fite already has licensing agreements in place for up to approximately \$22 million in upfront and milestone payments, plus royalties upon commercialization for CF101 for anti-inflammatory indications with Seikagaku Corporation in

Japan

and with Kwang Dong Pharmaceutical Co. Ltd in

South Korea

. Can-Fite has already received approximately

\$8 million

in upfront and milestone payments to date.

"We are disappointed from the fact that the phase 3 clinical trial for the treatment of Dry Eye Syndrome did not meet the endpoints. We intend to learn the trial results and extract from the clinical data received the lessons required for the successful advancement of Can-Fite's compounds in various indications. The fact that the safety profile of CF101 remains high and is consistent is very encouraging and emphasizes an important advantage of CF101 compared to other drugs on the market. Our recently released positive data from our RA phase IIb clinical study and the positive interim analysis of data with respect to CF101 for the treatment of psoriasis, in which half of the patients treated with CF101 showed clinically meaningful improvement, both demonstrate the potential of the A3AR agonist CF101 for autoimmune inflammatory indications. We believe in the platform technology and will continue to develop it for the appropriate indications," 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 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 Can-Fite.

**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

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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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