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# Can-Fite Reports Positive Results from Further Analysis of Phase II/III Psoriasis Trial

**Data suggest CF101 as potential first-line systemic therapy for patients with moderate-severe psoriasis; Company prepares protocol of next advanced psoriasis trial**

PETACH TIKVA, Israel, April 27, 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 favorable data from further analysis of its Phase II/III double-blind, placebo-controlled study designed to test the efficacy of CF101 in patients with moderate-to-severe plaque psoriasis.

The study included 326 patients through 17 clinical centers in the U.S., Europe, and Israel with a duration of 32 weeks where the primary endpoint was after 12 weeks. On March 30, 2015, Can-Fite announced the study did not meet its primary endpoint of a statistically significant improvement in the Psoriasis Area Severity Index (PASI) 75 score relative to placebo after 12 weeks of treatment. However, based on further analysis of the efficacy and safety results from the study as described below, Can-Fite intends to continue the development of CF101 for the treatment of psoriasis and has initiated work on the design of the next advanced-stage clinical trial protocol.

Further analysis of the entire study period revealed that by 32 weeks of treatment with CF101, 33% of the patients achieved PASI 75 while the mean percent of improvement in PASI score was 57% ( $p < 0.001$ ). This was a statistically significant cumulative and linear improvement during weeks 16 to 32.

Most significantly, by week 32 of the study, 20% of the study patients reached PASI 90, a result demonstrating a response rate of 90% clearing of skin lesions. PASI 90 is one of the most stringent and difficult to meet clinical endpoints for measuring responses to psoriasis treatments. Moreover, the PASI 90 subset analysis further suggests a higher and significant ( $p = 0.026$ ) CF101 response rate of 27% among patients previously untreated with systemic psoriasis therapy compared to patients pre-treated with systemic drugs. The Company believes this presents the opportunity that CF101 can be developed as a first-line systemic therapy for patients with moderate-severe psoriasis and for patients who do not want to be treated with the current systemic drugs due to safety issues. Currently there is no universally accepted first-line systemic therapy for patients diagnosed with psoriasis, and therefore CF101, an orally bioavailable drug with an excellent safety profile can be positioned for this unmet need.

"The cumulative and linear improvement in CF101's efficacy treating moderate to severe psoriasis over a longer period of time is a very significant finding for Can-Fite and the psoriasis treatment market. Based on the very favorable safety data on CF101 from this and

other trials, coupled with its oral administration, we believe CF101 offers a valuable potential treatment solution for psoriasis and we are committed to continuing our development program," stated Can-Fite CEO Dr. Pnina Fishman. "We are particularly encouraged by the new data that show CF101 could serve as a first-line therapy for moderate-severe psoriasis based on the higher efficacy in patients who were previously not treated with systemic therapy."

## **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](http://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.

#### Contact

Can-Fite BioPharma

Motti Farbstein

[info@canfite.com](mailto:info@canfite.com)

+972-3-9241114

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