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Can-Fite Completes Patient Enrollment in its Phase II/III Psoriasis Trial; Final Results are expected in Q1 2015

Previously released interim results from the trial showed positive safety and efficacy; 300 patients with moderate to severe disease were enrolled in the study

PETACH TIKVA, Israel, June 17, 2014 /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 it has finalized enrollment in its Phase II/III trial of CF101 for the treatment of psoriasis with over 300 patients through 17 clinical centers in the U.S., Israel and Europe. Top line results from the trial are expected in the first quarter of 2015.

The psoriasis therapeutic market was worth $3.6 billion in 2010 and is forecast to grow to $6.7 billion by 2018, according to Global Data. The market is dominated by biological drugs that are primarily administered via intravenous injection (IV) and have potential side effects.

"Based on our studies to date, we believe that, if approved, CF101 would have the potential to offer an oral, safe and well-tolerated treatment alternative for people living with psoriasis," stated Can-Fite CEO Dr. Pnina Fishman. "Now that we have completed patient enrollment, we hope that the upcoming conclusion of this Phase II/III trial will yield additional data which may prove the efficacy of CF101 in the treatment of psoriasis."

About the Trial

The Phase II/III double-blind, placebo-controlled study is designed to test the efficacy of CF101 in 300 patients with moderate-to-severe plaque psoriasis. The first study cohort was comprised of three arms with patients receiving: 1 mg of CF101; 2 mg of CF101; and placebo. All patients receiving placebo were switched to either 1 mg or 2 mg of CF101 after 12 weeks. The primary efficacy endpoints are a statistically significant improvement in standard measures used by dermatologists to assess psoriasis including the Psoriasis Area Sensitivity Index (PASI) score and the Physicians' Global Assessment (PGA) score as well as various safety parameters.

Interim safety and efficacy results were released from the first 103 patients who completed 24 weeks of treatment in the trial. The positive clinical effects of CF101 at the 2 mg dose relative to placebo were observed through PASI and PGA scores, with the responses accumulating steadily over the 24-week treatment period. To allow the trial to meet its full objectives, the study protocol has been amended to enroll patients for the 2 mg dose and placebo administration for an extended study period of 32 weeks.

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. 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 and inflammatory diseases. The Company's CF101 is in 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 commencing 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. 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

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