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Can-Fite's Phase III ACRobat Trial in Rheumatoid Arthritis Approved by Institutional Review Board

PETACH TIKVA, Israel, April 25, 2017 /PRNewswire/ --

- ***Barzilai Medical Center in Israel ready to enroll patients***
- ***IRB approvals in European and Canadian medical centers expected to follow***
- ***Can-Fite to conduct Investigator Meeting in Europe with approximately 100 doctors from participating clinical sites***
- ***Piclidenoson being evaluated as first line therapy and replacement for current standard of care Methotrexate***

Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today that Barzilai Medical Center's Institutional Review Board (IRB) has approved the Phase III ACRobat trial protocol and patient enrollment for the study at the 627-bed hospital in Ashkelon, Israel. This marks the first of several expected IRB approvals in medical centers in Israel, Europe and Canada.

Piclidenoson is being developed as a first line therapy for rheumatoid arthritis and replacement for the current standard of care, Methotrexate (MTX). MTX is the most widely used drug for rheumatoid arthritis, with approximately 90% of rheumatoid arthritis patients receiving MTX at some point in their disease, according to the Arthritis Foundation of America.

However, 40-50% of patients stop taking MTX after five years, primarily due to the presence of serious side-effects, as indicated in some published studies. Other studies show that between 10% and 30% of patients are intolerant of MTX, creating a significant need in the market for a new, safe and effective treatment option.

The primary endpoint of ACRobat is low disease activity after 12 weeks of treatment in patients dosed with Piclidenoson compared to those dosed with MTX. Piclidenoson at 1 mg and 2 mg, or placebo, will be administered twice daily, and MTX or placebo will be administered once weekly. The total study duration will be 24 weeks in order to provide more data on long term efficacy and safety. This randomized, double-blind, active and placebo-controlled study will enroll approximately 500 patients through clinical sites in Israel, Europe and Canada. On May 24, 2017, Can-Fite plans to conduct an Investigator Meeting in Europe. During the meeting, approximately 100 doctors participating as clinical investigators in the global study will partake in a series of educational sessions regarding Piclidenoson and the ACRobat protocol.

"Piclidenoson has demonstrated its safety profile in over 1,000 patients and prior clinical data show its potential to be as effective, or more effective, than MTX in treating rheumatoid arthritis. Our ACRobat trial is powered to demonstrate Piclidenoson's potential as a first line therapy and superior alternative to MTX, which unfortunately can have severe side effects for patients who need a long-term treatment solution," stated Can-Fite CEO Dr. Pnina Fishman.

Rheumatoid arthritis is a treatment market forecast to reach $34.6 billion by 2020.

About Piclidenoson (CF101)

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical studies. Piclidenoson is currently under development for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis and psoriasis, both set to commence Phase 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 autoimmune-inflammatory indications, oncology and liver diseases as well as sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is headed into Phase III trials for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug Namodenoson is in a Phase II trial for patients with liver cancer and is slated to enter another Phase II for the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH). Namodenoson has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. Namodenoson has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. CF602, the Company's third drug candidate, has shown efficacy in the treatment of erectile dysfunction in preclinical studies These drugs have an excellent safety profile with experience in over 1,000 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, market risks and uncertainties and Can-Fite's ability to satisfy all the conditions to the closing of the proposed offering, 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

+972-3-9241114