February 8, 2017

Can-Fite Gears Up for ACRobat, its Phase III Trial of Piclidenoson in Rheumatoid Arthritis

-- Patient enrollment to commence Q2 2017

-- Piclidenoson supply for the study is completed and paid for

-- Total budget for the Phase III study is $5M

PETACH TIKVA, Israel, Feb. 8, 2017 /PRNewswire/ -- 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 the Company is ready to commence patient enrollment in the second quarter of 2017 in its global Phase III trial of its lead drug candidate Piclidenoson as a first line treatment for rheumatoid arthritis. The trial, titled ACRobat, will enroll approximately 500 patients in Europe, Canada and Israel.

The estimated cost of the entire Phase III study is approximately $5 million. This includes the cost of the global clinical research organizations that have been engaged to help conduct ACRobat. The required supply of Piclidenoson has already been manufactured and paid.

Piclidenoson is being developed as a first line therapy and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis. The primary endpoint of ACRobat, a randomized, double-blind, active and placebo-controlled study, 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.

"We are eager to commence our Phase III rheumatoid arthritis trial in the second quarter. We believe Piclidenoson can offer a superior alternative to MTX, which is used at some point by approximately 90% of rheumatoid arthritis patients. MTX is an oncology drug known to induce severe adverse events. Piclidenoson's well established and excellent safety profile, as demonstrated in previous clinical studies in more than 1,000 patients, combined with a potential for efficacy equal to or better than MTX, positions Piclidenoson as a potential future first line therapy of choice for doctors treating rheumatoid arthritis," stated Can-Fite CEO Dr. Pnina Fishman.

Although approximately 90% of rheumatoid arthritis patients receive MTX at some point in their disease according to the Arthritis Foundation of America, 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.

Rheumatoid arthritis is a treatment market forecast to reach $38.5 billion by 2017.

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 (completed Phase II) and psoriasis (completed 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 lead drug candidate, Piclidenoson, is scheduled to enter Phase III trials in 2017 for two indications, rheumatoid arthritis and psoriasis. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug Namodenoson is in Phase II trials for patients with liver cancer and is slated to enter Phase II for the treatment of 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 and is being prepared for an IND submission to the FDA and a Phase I trial. 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.

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