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Can-Fite Reaches Agreement with EMA on Pivotal Phase III Clinical Trial with Piclidenoson (CF101) in Rheumatoid Arthritis

- EMA suggests development of Piclidenoson as a first line therapy and alternative for methotrexate, the standard of care for rheumatoid arthritis

- Methotrexate is the most widely used rheumatoid arthritis drug worldwide

- ~ 90% of rheumatoid arthritis patients take the drug at some point of their disease

PETACH TIKVA, Israel, June 1, 2016 /PRNewswire/ -- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, today announced that it has reached agreement with the European Medicines Agency (EMA) on the final design of a global pivotal Phase III trial for its lead drug candidate, Piclidenoson (CF101), in rheumatoid arthritis. Following a successful meeting with the EMA, and based on guidance received from the European health regulatory body, Can-Fite plans to evaluate the efficacy and safety of Piclidenoson compared to methotrexate (MTX) in the treatment of early rheumatoid arthritis patients. The Company intends to initiate the Phase III trial in the second or third quarter of 2016.

The EMA suggested Piclidenoson should be developed as an alternative to MTX, the most widely prescribed rheumatoid arthritis drug in the world. The EMA further suggested that this pivotal Phase III study will serve as the first of two pivotal studies required for drug approval.

The planned trial will be a randomized, double-blind, active and placebo-controlled Phase III trial to establish non-inferiority of Piclidenoson versus MTX, conducted in approximately 500 patients worldwide. Piclidenoson at 1 mg and 2 mg or placebo will be administered twice daily, and MTX or placebo will be administered once weekly. The primary endpoint will be Low Disease Activity as measured by Disease Activity Scores at week 12. The trial will also evaluate key secondary endpoints, including American College of Rheumatology (ACR) score 20, 50 and 70 and the correlation between A3AR expression at baseline and patients' response to Piclidenoson. To establish longer-term clinical efficacy and safety, the trial will continue for a period of 24 weeks.

"Our successful meeting with the EMA represents an important milestone in our registration plan for Piclidenoson, which will encompass two pivotal Phase III studies that will be

submitted to the regulatory authorities. Our studies will be conducted worldwide and we are confident that this development program maximizes Piclidenoson's potential for success in Phase III," stated Can-Fite CEO, Dr. Pnina Fishman.

MTX is currently considered the first-line of therapy for the treatment of rheumatoid arthritis. According to the Arthritis Foundation of America, approximately 90% of rheumatoid arthritis patients receive MTX as part of their treatment regimen at some point to treat their disease. However, studies indicate that 40-50% of patients stop taking MTX after only five years, primarily due to the presence of serious side-effects. Other studies show that between 10% and 30% of patients are intolerant to MTX, creating a significant need in the market for a new, safe and effective treatment option.

Rheumatoid arthritis is a chronic, systematic, autoimmune inflammatory disease that manifests as joint pain, stiffness and swelling. According to Visiongain, a leading market research firm, the global rheumatoid arthritis market is forecasted 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 2016 for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug CF102 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). CF102 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. CF102 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, 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