

August 7, 2017

Can-Fite Successfully Completes Human Cardiodynamic Safety Trial for Piclidenoson

Strong safety results clear Piclidenoson to commence Phase III efficacy trials in the treatment of Rheumatoid Arthritis and Psoriasis

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [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, today announced it has successfully concluded a cardiodynamic trial for its lead drug candidate Piclidenoson (CF101). The trial is a regulatory safety requirement of both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) prior to the initiation of Phase III studies. Based on the favorable safety data from this cardiodynamic trial, Can-Fite is now cleared to initiate two global Phase III studies for Piclidenoson: the ACRobat trial in rheumatoid arthritis; and the Comfort trial in psoriasis.

The cardiodynamic trial was a placebo-controlled crossover study using precise methodology to determine the effect of Piclidenoson on electrocardiograms of healthy volunteers. Such a study is required by U.S. and European regulatory authorities before, or in parallel with, Phase III to establish cardiac safety in humans prior to registration for marketing approval. The primary objective of the trial was to assess whether Piclidenoson causes a delay in cardiac repolarization, as manifested by prolongation of the QT interval of the electrocardiogram. A drug-induced delay in cardiac repolarization creates an electrophysiological environment that can lead to the development of ventricular cardiac arrhythmias.

In this study, Piclidenoson doses were up to 3-fold higher than the highest dose expected to be used in the Company's registration-directed clinical trials. In yet another indication that Piclidenoson has a favorable human safety profile, this cardiodynamic trial showed that the Company's highest projected Piclidenoson dose had no clinically significant adverse electrocardiographic effects, thereby enabling progression into definitive Phase III trials.

"Data from this standard safety study required by the FDA and EMA clearly demonstrated and reinforced the safety profile of Piclidenoson. Our lead drug candidate has already been shown to be safe and well tolerated in over 1,000 patients to date," stated Can-Fite Medical Director Dr. Silverman. "We look forward to commencing patient recruitment and dosing for our Phase III trials of Piclidenoson in rheumatoid arthritis and psoriasis."

Rheumatoid arthritis is a treatment market forecast to reach \$38.5 billion by 2017. The psoriasis market is forecast to be \$8.9 billion in 2018 and Otezla® sales are estimated to be \$2.35 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 (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 a Phase III trial for rheumatoid arthritis in 2017 and a Phase III trial for psoriasis in early 2018. 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 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. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our

ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed 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.

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20170807005253/en/>

Can-Fite BioPharma

Motti Farbstein, +972-3-9241114

info@canfite.com

Source: Can-Fite BioPharma Ltd.