

Can-Fite Advances Towards a Pivotal Phase III Clinical Trial in Psoriasis with Piclidenoson (CF101) Following Reaching Agreement with EMA

- Phase III clinical study designed to establish Piclidenoson is superior to placebo as primary endpoint and non-inferior to Otezla® at week 32 as secondary endpoint**
- Global psoriasis market estimated to reach \$9 billion by 2018**

PETACH TIKVA, Israel, Nov. 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 and liver diseases, cancer and sexual dysfunction, today announced that it has reached an 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 the treatment of psoriasis. Can-Fite intends to initiate the Phase III trial in the second half of 2017.

The planned Phase III trial is a randomized, double-blind, placebo- and active-controlled study that will investigate the efficacy and safety of daily Piclidenoson administered orally as compared to placebo as its primary endpoint and as compared to apremilast (Otezla®) as its secondary endpoint in approximately 400 patients with moderate-to-severe plaque psoriasis. Medication is to be taken orally twice daily for 32 weeks in a double-blinded fashion. The primary end point will be the proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response of $\geq 75\%$ (PASI 75) vs. placebo at week 16. The secondary endpoints will include non-inferiority to Otezla® on week 32 and efficacy and safety data for CF101 through the extension period of up to 48 weeks of treatment. Patients will be selected to the study based on over expression of the A3AR biomarker.

The rationale of comparing Piclidenoson to Otezla®, the recently registered oral drug marketed by Celgene, is based on data from Can-Fite's prior Phase II/III study that showed at weeks 24 and 32, Piclidenoson's efficacy as measured by PASI compares well to Otezla® in its Phase III trial.

"The higher dosage of Piclidenoson together with the utilization of A3AR as a predictive biomarker for patient selection are expected to be important in yielding a faster and efficacious response," stated Can-Fite CEO Dr. Pnina Fishman. "We believe the agreed study design for this pivotal Phase III trial positions us well to demonstrate Piclidenoson's superior and faster accumulation of efficacy. Given that Piclidenoson has exhibited excellent safety in prior clinical trials, we believe that this presents an opportunity to treat patients who need to use drugs for a long time for this chronic disease."

The global psoriasis market is estimated to reach \$9 billion by 2018 (Visiongain), and Otezla® sales are estimated to be \$2.35 billion by 2020 (DrugAnalyst).

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. The rheumatoid arthritis Phase III protocol has recently been agreed with EMA. 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.

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