

April 25, 2018

Can-Fite's Piclidenoson Mechanism of Action in Psoriasis Published in 'Journal of Immunology Research'

Phase III Psoriasis Study Scheduled for Initiation During this Quarter

Psoriasis Therapeutic Market is Estimated to Reach \$11.4B in 2020

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory and liver diseases, today announced the publication of a paper entitled "Inhibition of IL-17 and IL-23 in Human Keratinocytes by the A3 Adenosine Receptor Agonist Piclidenoson" in the Journal of Immunology Research, a peer-reviewed, online open access journal.

The paper presents pre-clinical data that have been accumulated and [reported earlier](#), demonstrating that Piclidenoson mechanism of action is manifested by the inhibition of two inflammatory cytokines, interleukin 17 (IL-17) and interleukin 23 (IL-23) which are known to play a major role in the inflammatory process of psoriasis. Currently, some of the novel biologic drugs on the market to treat psoriasis are injectable immune-modulators, which block IL-17 and IL-23. These systemic drugs offer good efficacy, however, as biologics they can cause serious side effects. The psoriasis therapeutic market is estimated to reach \$11.4B in 2020 according to Visiongain.

Piclidenoson binds to the Gi protein associated A3 adenosine receptor (A3AR), which is over-expressed in psoriasis patients. This binding action has shown to induce a robust anti-inflammatory effect by inhibiting IL-17 and IL-23 as demonstrated in the in-vitro studies presented in the paper. An orally administered small molecule drug, Piclidenoson, potentially offers safety superior to biologics as shown in clinical studies in more than 1,000 people.

The paper can be accessed online at: <https://www.hindawi.com/journals/jir/aip/2310970/>.

The Company has completed the preparatory work for its COMFORT Phase III Psoriasis study, designed to evaluate the efficacy and safety of daily Piclidenoson, administered orally compared to Apremilast (Otezla®) and placebo in around 400 patients with moderate-to-severe plaque psoriasis. The study will be conducted in 5 countries in Europe, Israel and Canada. The study protocol has been already submitted to the IRB in Israel, which will be the first country and patient enrollment is scheduled to be initiated this quarter. Submissions in Europe and Canada will follow shortly.

Pnina Fishman, PhD., Can-Fite CEO commented, "We believe this pre-clinical study provides a strong rationale for the use of Piclidenoson in patients suffering from psoriasis. We look forward to initiating our Phase III study this quarter."

[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 (Phase III, ongoing) and psoriasis (Phase III to be initiated shortly).

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CFBI) is an advanced clinical stage drug development Company with a platform technology that is designed to address multibillion-dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis during the second quarter of 2018. Can-Fite's liver cancer drug, Namodenoson, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and 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 HCC 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 the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. 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: our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on

acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; 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 strategic partnerships and other 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; 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.

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Source: Can-Fite BioPharma Ltd.