September 2, 2021

Can-Fite Completes Patient Enrollment in Phase III Psoriasis Study

- ***Positive interim analysis data was released in October 2020 based on results from 200 patients***
- ***Topline results expected Q1 2022***

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, cancer and liver diseases, today announced it has completed enrollment of all patients (>400) planned for its Phase III Comfort™ study in patients with moderate to severe plaque psoriasis.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210902005275/en/

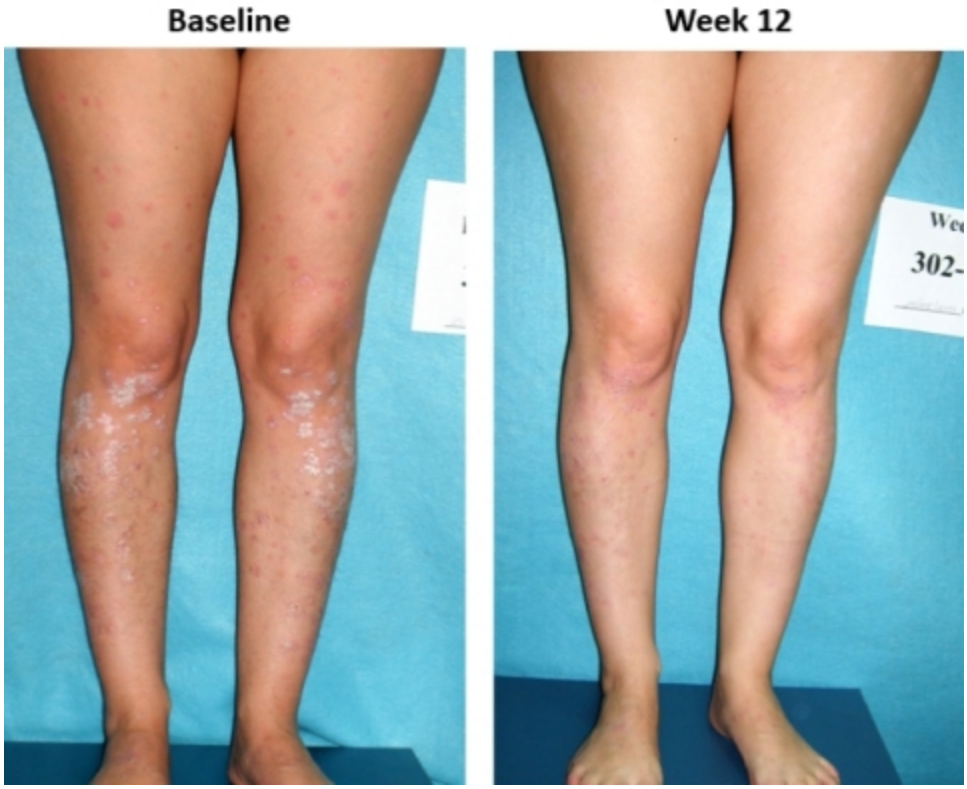

Image from prior Phase II clinical trial of Piclidenoson of patient's skin before treatment and at week 12 following treatment (Photo: Business Wire)

Positive interim data analysis from this Phase III study was released by Can-Fite in October 2020. The Independent Data Monitoring Committee (IDMC) conducted a pre-planned interim analysis of 200 patients' data and recommended, based on the positive data, to continue the study. At this point, the Company has completed the enrolment of all patients for this study and plans to release topline results in Q1 2022.

The randomized, double blind, active and placebo controlled study is being conducted in Europe, Israel, and Canada. The study's primary endpoint is the proportion of patients who achieve a PASI score response of ≥75% (PASI 75) vs. placebo at week 16. Secondary endpoints include non-inferiority to Otezla® in weeks 16 and 32. Patients enrolled in the study have been

selected based on their over-expression of the A3 adenosine receptor (A3AR), Can-Fite's therapeutic target.

"Because psoriasis is a chronic condition, it's important for effective treatments to also show good safety and minimal side effects as they are used long term. While injectable biologics have been effective, their potential side effects make them less optimal for long-term use. We believe that based on the positive interim analysis, Piclidenoson, as a small molecule oral drug, shows great potential to demonstrate both efficacy and safety. We look forward to announcing topline results in the first quarter of 2022," stated Can-Fite CEO Dr. Pnina Fishman.

Otezla generated $2.2 billion in sales in 2020. According to iHealthcareAnalyst, the psoriasis therapeutic market is estimated to reach $11.3 billion by 2025. Piclidenoson has been out-licensed for the indication of psoriasis in major markets including Canada, Europe, and Asia with deal terms including potential upcoming milestone payments and double-digit royalties upon regulatory approval.

About Piclidenoson

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. It is currently being evaluated in a multinational Phase III study as a treatment for moderate to severe psoriasis and a Phase II U.S. study for the treatment of moderate to severe COVID-19.

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 multi-billion dollar markets in the treatment of cancer, liver, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and a Phase IIb trial 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. These drugs have an excellent safety profile with experience in over 1,500 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 impact of the COVID-19 pandemic; 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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