August 22, 2022

Can-Fite Selected to Present the Positive Psoriasis Phase III Data at the 31st European Academy of Dermatology and Venerology Congress

- ***Presentation by study's co-author Dr. Kim Papp, a Key Opinion Leader who has completed over 150 studies and worked on numerous drugs now on the market***
- ***Dr. Papp is designing Can-Fite's pivotal Phase III psoriasis registration trial***

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, announced today that Dr. Kim A. Papp, MD, PhD, will present late-breaking news at the 31st European Academy of Dermatology and Venerology (EADV) Congress from an ongoing analysis of Can-Fite's recently completed Phase III COMFORT™ study in which Piclidenoson met its primary endpoint with statistically significant improvement over placebo in psoriasis patients. The presentation titled "Treatment of plaque psoriasis with piclidenoson: Efficacy and safety results from a phase 3 clinical trial (COMFORT)" will be delivered on September 10, 2022, during the Late Breaking News session from 8:30 am to 11:45 am in Milan, Italy.

The study is co-authored by numerous dermatology key opinion leaders, researchers, and investigators, in Europe, Israel, and Canada, including Dr. Papp who is leading the design of Can-Fite's pivotal Phase III psoriasis registration trial, which will be submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for market clearance of Piclidenoson in the treatment of moderate to severe psoriasis.

Based in Waterloo, Ontario, Canada, Dr. Papp has over 25 years' experience as a Principal Investigator. Internationally renowned as a Key Opinion Leader in clinical research, Dr. Papp has conducted over 70 international dermatology studies on a wide range of dermatological disorders. The K. Papp Clinical Research center is considered one of the top clinical research centers in the world. Instrumental in improving and refining study designs, Dr. Papp has completed over 150 research studies on 50 compounds and has worked on new treatments that are now available and helping tens to hundreds of thousands of patients with their condition.

"As we continue to analyze the data from our COMFORT study, we are gaining additional insight into Piclidenoson's efficacy and safety. Upon completing the latest sub-analysis, we look forward to Dr. Papp presenting new data at EADV," stated Can-Fite CEO Dr. Fishman. "As we work closely with Dr. Papp on finalizing the pivotal Phase III study protocol, we are grateful to the talented group of researchers who helped conduct COMFORT and analyze the data for this study."

About Piclidenoson

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with an excellent safety profile demonstrating evidence of efficacy in Phase II clinical studies. The drug's mechanism of action entails inhibition of the inflammatory cytokines interleukin 17 and 23 (IL-17 and IL-23) and the induction of apoptosis of patients' skin cell keratinocytes involved with the disease pathogenicity.

About the Phase III COMFORT™ Study

The COMFORT™ CF101-301PS, is a Phase III randomized, double-blind, placebo- and active-controlled study of the efficacy and safety of daily Piclidenoson (CF101) administered orally in patients with moderate-to-severe plaque psoriasis. The primary objectives of this study are to evaluate the efficacy of oral Piclidenoson 2 mg or 3 mg twice daily (BID) in patients with moderate-to-severe plaque psoriasis, compared with placebo, as determined by the proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response of ≥75% (PASI 75) at Week 16 (superiority); and evaluate the safety of oral Piclidenoson in this patient population. The secondary objectives of this study are to evaluate the efficacy of oral Piclidenoson 2 mg or 3 mg BID, compared with placebo, as determined by the proportion of subjects who achieve, respectively, PASI 50, Physician Global Assessment (PGA) score of 0 or 1, and improvement on the Psoriasis Disability Index (PDI) at Week 16 (superiority); evaluate the efficacy of oral Piclidenoson 2 mg or 3 mg BID, compared with Otezla (apremilast), as determined by the proportion of subjects who achieve PASI 75, PGA score of 0 or 1, PASI 50, and improvement in PDI at Weeks 16 and 32 (non-inferiority); and evaluate the efficacy and safety data for Piclidenoson through the extension period of up to 48 weeks of treatment.

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, and inflammatory disease. The Company's lead drug candidate, Piclidenoson recently reported topline results in a Phase III trial for psoriasis. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH), and enrollment is expected to commence in a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer. 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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Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

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