September 12, 2022

Can-Fite: New Phase III Psoriasis Data Showing Superior Safety & Improved Efficacy Presented by KOL Dr. Papp at the 31st European Academy of Dermatology

- Dr. Papp: “The safety results on Piclidenoson and its progressive effectiveness over the study period position it as unique among the current treatment options especially given the chronic nature of psoriasis which can necessitate long-term treatment.”
- Piclidenoson has a safety profile similar to placebo and is better tolerated than Otezla®
- Efficacy of Piclidenoson is similar to Otezla in psoriasis patients with severe disease

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, presented new data from the Company’s recently completed Phase III COMFORT™ study at the late-breaking news session of the 31st European Academy of Dermatology and Venerology (EADV) Congress. Can-Fite previously reported the COMFORT™ study met its primary endpoint with Piclidenoson showing a statistically significant improvement over placebo in psoriasis patients. Piclidenoson is advancing into a pivotal Phase III psoriasis registration trial. The protocol, which is being designed by Dr. Papp, 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.

The following is a summary of key findings presented at EADV on September 10, 2022 in Milan, Italy during Dr. Papp’s presentation titled “Treatment of plaque psoriasis with piclidenoson: Efficacy and safety results from a phase 3 clinical trial (COMFORT)”:

- The COMFORT™ Phase III study met its primary endpoint of superiority vs. placebo at 16 weeks, p=0.037
- Patients treated with Piclidenoson showed an improving progressive response over time, and as psoriasis is a chronic disease that may require long-term treatment, this is an important finding
- Piclidenoson demonstrated an excellent safety profile, overlapping that of the placebo-treated group.
- Piclidenoson had a significantly better tolerability profile than Otezla, as GI-related adverse events were 1% for Piclidenoson vs. 6% for Otezla, nervous system disorders were 0.7% for Piclidenoson, 9.9% for Otezla and 3.3% for the placebo. The discontinuation rate was significantly higher for Otezla vs. Piclidenoson
- In the secondary endpoint of achieving a PASI 75 response (representing a 75% reduction in psoriasis severity) at week 32, in the whole patient population, Piclidenoson was inferior to Otezla; however, in a sub-group analysis of patients who had PASI>25 (more severe psoriasis) at baseline, Piclidenoson had a comparable

response to Otezla
- In the secondary endpoint of achieving psoriasis disability index (PDI) response at week 32, Piclidenoson was comparable to Otezla

Dr. Papp commented, “The safety results on Piclidenoson and its progressive effectiveness over the study period position it as unique among the current treatment options especially given the chronic nature of psoriasis which can necessitate long-term treatment.”

Dr. Papps’s presentation was based on a study co-performed by numerous dermatology investigators, in Europe, Israel, and Canada.

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.

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, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, 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; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the "Risk Factors" section of Can-Fite's Annual Report on Form

20-F filed with the SEC on March 24, 2022 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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