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Can-Fite: Top Scientific Journal Published Positive Data from the COMFORT-1 Phase III Psoriasis Study

Piclidenoson is a small molecule safe oral drug suitable for the chronictreatment of patients who suffer from moderate to severe plaque psoriasis.

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced that the *Journal of the European Academy of Dermatology and Venereology*(EADV) published an article titled “Efficacy and safety of piclidenoson in plaque psoriasis: Results from a randomized phase 3 clinical trial (COMFORT-1)”. EADV is a top ranked peer reviewed journal (impact factor 9.2) that publishes articles on clinical and basic science topics in dermatology. Article Link.

The article’s first author, Dr. K.A Papp, is an internationally renowned key opinion leader in the psoriasis field and was the engine for some registered drugs on the market for this devastating skin disease.

The EADV article presents the safety and efficacy of Piclidenoson in the randomized, placebo- and active-controlled, double-blind Phase III COMFORT-1 trial. As previously reported, the study met its primary endpoint which was the proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI) from baseline (PASI-75) at Week 16 (3 mg BID dose: PASI 75 rate of 9.7% vs. 2.6% for Piclidenoson vs. placebo, p=0.037). Piclidenoson’s efficacy continued to increase throughout the study period in a linear manner with an excellent safety and tolerability profile.

Currently, Piclidenoson is being evaluated in COMFORT-2 a pivotal Phase III study that has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

“We are very much encouraged by the excellent data in the first Phase III study demonstrating the significant effect of Piclidenoson in psoriasis,” stated Dr. Fishman, Can-Fite’s Chief Scientific Officer and Executive Chairman. “We plan to start treating patients in our pivotal trial very shortly and hope that Piclidenoson, with its safety and efficacy profile, given orally to psoriasis patients will become a drug of choice.”

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 and III psoriasis 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 disease pathogenicity. Based on preclinical

efficacy data, Piclidenoson is also being co-developed for the treatment of Lowe Syndrome, a rare genetic disease.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF) 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 and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of steatotic liver disease (SLD), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic 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 1,600 patients in clinical studies to date. For more information please visit: www.canfite.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 30, 2023 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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