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# Can-Fite Initiates Pivotal Phase 3 Psoriasis Study of its Oral Drug Piclidenoson with FDA & EMA-Approved Protocol

***The psoriasis market is estimated at \$30 Billion by 2030 and has shifted significantly to oral drugs***

Ramat Gan, Israel, March 24, 2025 (GLOBE NEWSWIRE) -- [Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE: CANF), a biotechnology company developing a pipeline of proprietary small molecule drugs targeting oncological and inflammatory diseases, today announced that it initiated a pivotal phase 3 psoriasis study of its oral drug Piclidenoson with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) - approved clinical study protocol. The study will enroll patients with moderate to severe plaque psoriasis. Patient enrolment will be initiated in Europe and US and Canada expected to follow.

The study is a randomized, double-blind, placebo-controlled Phase 3 aimed at demonstrating clinical safety and efficacy for the treatment of patients with moderate to severe plaque psoriasis. Patients will be treated with 3 mg twice daily orally Piclidenoson tablets or placebo. The co-primary efficacy objectives of this study are the proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response of  $\geq 75\%$  (PASI 75) and the proportion of subjects who achieve a Static Physician's Global Assessment (sPGA) at of 0 or 1 at Week 16. The FDA requested two Phase 3 safety and efficacy studies and also encouraged the Company to enroll adolescent patients due to the strong safety profile of the drug demonstrated over the development history and prior clinical studies.

"We are excited to initiate the Phase 3 study and we believe that Piclidenoson's oral dosage and excellent safety record, together with its progressive effectiveness over time, make it an ideal drug for the chronic treatment of psoriasis," stated Can-Fite CEO Motti Farbstein.

Upon positive conclusion of the Phase 3 program, the Company plans to submit a New Drug Application (NDA) to the U.S. FDA and Marketing Authorization Plan (MAA) to the EMA.

## About Piclidenoson

Piclidenoson is a novel, robust anti-inflammatory 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 Phase III 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 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 reported topline results in a Phase III trial for psoriasis and commenced a pivotal Phase III trial. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in 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: <https://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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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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