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Can-Fite Submits Market Registration Plan to European Medicines Agency for Piclidenoson in the Treatment of Psoriasis; FDA Submission to Follow

As an oral treatment with an excellent safety and efficacy profile, Piclidenoson has potential for strong market position in $26 B psoriasis treatment market

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 inflammatory, cancer and liver diseases, announced today it has submitted a market registration plan to the European Medicines Agency (EMA) for its lead drug candidate Piclidenoson in the treatment of moderate to severe psoriasis. A submission to the U.S. Food and Drug Administration (FDA) will follow.

Registration plans for both the EMA and FDA include final efficacy and safety results from Can-Fite's successful COMFORT™ Phase III study and the protocol for the Company's upcoming Phase III pivotal trial together with a request for registration advice from the regulators. Current chemistry, manufacturing, and controls (CMC), nonclinical data, and human pharmacokinetic data are also included.

Can-Fite recently reported topline results from its Phase III COMFORT™ study which met its primary endpoint with statistically significant improvement over placebo in psoriasis patients and an excellent safety profile for Piclidenoson. The Phase III COMFORT™ data point towards a better safety profile for Piclidenoson as compared to Otezla, the leading oral therapy for psoriasis on the market today, as Otezla induced: 1) gastro-intestinal adverse events in 6% of patients compared with 1% in patients treated with placebo or Piclidenoson; and 2) 9.9% nervous system disorders in the Otezla vs. 0.7% in the Piclidenoson treated patients.

"Piclidenoson's clinical trial results to date demonstrate its highly favorable safety profile which is similar to placebo, superior to oral Otezla, and based on published studies, far superior to biologics. Efficacy results from the COMFORT™ study show Piclidenoson is most effective longer term and with the most severe cases, suggesting it can be a preferred choice for the safe and effective treatment of this chronic condition," stated Can-Fite's Medical Director, Dr. Michael Silverman.

"This submission represents an important step toward the pivotal Phase III study and subsequent marketing approval of Piclidenoson," said Dr. Pnina Fishman, CEO & CSO of Can-Fite BioPharma. "Given Piclidenoson's unique activity and safety profile, we believe the $26 billion psoriasis market where there is a need for a safe and efficacious drug is a meaningful commercial opportunity."

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, was 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 were 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 were 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: 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. 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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