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Can-Fite to Submit FDA & EMA Registration Plans for Piclidenoson in the Oral Treatment of Moderate to Severe Psoriasis

Further analysis of Phase III COMFORT™ data show Piclidenoson's superior safety profile and higher patient compliance compared to Otezla®

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 it is planning to submit its registration plans to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for its lead drug candidate Piclidenoson in the treatment of moderate to severe psoriasis.

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. Further analysis of the Phase III COMFORT™ data point towards a better safety profile for Piclidenoson as compared to Otezla, which induced gastro-intestinal adverse events in 6% of patients compared with 1% in patients treated with placebo or Piclidenoson. Discontinuation of treatment amongst patients treated with Otezla was significantly higher compared to that of the Piclidenoson treated patients.

A sub-analysis of the efficacy data that divided patients into those who had PASI>25 (more severe psoriasis) and PASI<25 (less severe) at baseline revealed that patients who started with higher PASI values at entry benefitted more from treatment with Piclidenoson as compared to placebo. This result demonstrates the efficacy of Piclidenoson in the treatment of patients with more severe disease.

In its registration plans, Can-Fite will submit the final efficacy and safety results from COMFORT™, a multicenter, randomized, placebo- and active-controlled, double-blind study that assessed the efficacy and safety of Piclidenoson in more than 400 adults with moderate to severe plaque psoriasis together with a request for registration advice to the FDA and EMA. Additionally, current chemistry, manufacturing, and controls (CMC), nonclinical data, and human pharmacokinetic data will be submitted to the agencies along with a pivotal Phase III protocol and other supporting clinical pharmacology plans.

"The additional safety and efficacy data that emerged following our topline Phase III results point to a strong market positioning for Piclidenoson among approved oral psoriasis drugs. Today, a large percentage of people living with psoriasis choose not to be treated with biologics due to reported serious side effects and the need to be treated in a clinic. Similarly, a percentage of patients using Otezla, the leading oral drug for psoriasis, suffer from

gastrointestinal issues and discontinue treatment. We believe that if Piclidenoson achieves its primary endpoint once again in an upcoming pivotal Phase III study, Piclidenoson will offer a safe and effective long-term treatment for people living with psoriasis, including those with the most severe cases," stated Can-Fite Medical Director, Dr. Michael Silverman.

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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