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FDA Clears Can-Fite to Commence Phase II COVID-19 Study

Piclidenoson has a robust anti-inflammatory effect with an excellent safety profile

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, today announced the U.S. Food and Drug Administration (FDA) has issued a "safe to proceed" notice for Can-Fite's Investigational New Drug (IND) application for a Phase II study of its lead drug candidate Piclidenoson in the treatment of COVID-19. The 40 patient, 28-day study is cleared to commence patient enrollment. Piclidenoson has been dosed in over 1,400 patients in prior trials as well as two ongoing Phase III studies for the treatment of rheumatoid arthritis and psoriasis.

"Having received this go-ahead from the FDA, and given the urgency of finding safe and effective treatments for COVID-19, we are eager to enroll and start treating patients," stated Can-Fite CEO Dr. Pnina Fishman. "We believe Piclidenoson's unique combination of anti-inflammatory effect and very favorable safety profile make it an ideal candidate to treat the complications of COVID-19."

The Phase II study titled "Piclidenoson for Treatment of COVID-19 – A Randomized, Double Blind, Placebo-Controlled Trial" is a pilot trial in a population of hospitalized patients who will receive Piclidenoson in addition to standard supportive care. Eligible patients are those with "moderate" COVID-19 per U.S. National Institutes of Health Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. Forty patients will be randomly assigned in a 1:1 ratio to the trial arms of Piclidenoson 2 mg twice daily or placebo, and treated for up to 28 days. Efficacy will be assessed through standard measures of clinical and respiratory status at Day 29, including the proportion of patients alive and free of respiratory failure, as well as the proportion discharged home without need for supplemental oxygen. Safety and pharmacokinetic data will also be captured.

About Piclidenoson

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical studies. Piclidenoson is currently under development for the treatment of autoimmune inflammatory diseases and for the treatment of COVID-19. It is being evaluated in multinational Phase III studies as a first line treatment to replace methotrexate in the treatment of rheumatoid arthritis, and as a treatment for moderate-to-severe psoriasis.

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, inflammatory disease and

COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint in a Phase II trial for the treatment of non-alcoholic steatohepatitis (NASH). 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 recent outbreak of coronavirus; 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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