## Can-Fite: Piclidenoson is Submitted for Compassionate Use Treatment for Coronavirus Patients in Israel

Rationale: Anti-Rheumatic and Ant-Viral Effects with Excellent Safety Profile

PETACH TIKVA, Israel--(BUSINESS WIRE)-- <u>Can-Fite BioPharma Ltd</u>. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, announced today that it has submitted Piclidenoson for a compassionate use program to treat coronavirus patients to the Institutional Review Board at Rabin Medical Center. If approved, the compassionate use program will be led by Dr. Dror Diker, M.D., Head of Internal Medicine D at the Rabin Medical Center. Patients would be treated at Rabin's Golda Hasharon Campus which is currently positioned to treat coronavirus patients in a specialized setting.

The rationale to treat coronavirus with Piclidenoson is based on the drug's anti-rheumatic effect, proven in earlier Phase II clinical studies conducted under an open IND with the U.S. Food and Drug Administration (FDA). A Phase III trial in agreement with the European Medicines Agency (EMA) and FDA for the treatment of rheumatoid arthritis is ongoing. Rheumatoid arthritis drugs are currently being evaluated as a treatment for the uncontrolled immune response and cytokine release syndrome (CSR) created by coronavirus. A scientific article published in *Drug Design, Development and Therapy* presented data on how Piclidenoson, by binding with the A3 adenosine receptor (A3AR), may inhibit CSR. China recently approved Roche's Actemra, a rheumatoid arthritis drug, to treat coronavirus patients with lung damage, and Roche has commenced a global Phase III study for Actemra to treat coronavirus patients with severe pneumonia.

Moreover, Piclidenoson has anti-viral effects, protected by U.S. patent US7589075, against other single stranded RNA viruses like coronavirus. Can-Fite is currently testing Piclidenoson's anti-viral effects against coronavirus in collaboration Dr. Kamel Khalili at Temple University, Lewis Katz School of Medicine in Philadelphia.

Piclidenoson has an excellent safety profile in over 1,400 patients treated for rheumatoid arthritis and other indications, with its most recent Drug Safety Update Report filed with regulatory agencies in February 2020 reporting the drug is well tolerated and has no emerging safety concerns.

Can-Fite has experience with compassionate use programs, as its drug candidate Namodenoson is currently treating advanced liver cancer patients through compassionate use, also at the Rabin Medical Center in Israel.

## 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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is 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: <a href="https://www.can-fite.com">www.can-fite.com</a>.

## **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 forwardlooking 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 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 CanFite'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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