February 3, 2020

Can-Fite Completes 50% Patient Enrollment in Phase III Rheumatoid Arthritis Study & Implements Interim Analysis

- ***Interim analysis by IDMC intended to improve study's efficiency and accelerate path towards regulatory approval***
- ***Piclidenoson evaluated as first line therapy and replacement for the current standard of care, methotrexate, the most widely used drug for rheumatoid arthritis***
- ***Rheumatoid arthritis is forecast to be $47 billion market in 2024***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (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 it has completed enrollment of approximately 50% of the 525 patients planned for its Phase III ACRobat™ trial to evaluate its drug candidate Piclidenoson as a first-line treatment for rheumatoid arthritis (RA).

An interim analysis is being implemented, and will be managed and monitored by an independent data monitoring committee (IDMC) that will have un-blinded access to the data. Piclidenoson continues to be well tolerated, with approximately 50% of patients enrolled to date and treatment durations up to 24 weeks, and no novel or cumulative safety concerns have emerged.

The Phase III ACRobat™ RA study is designed to establish Piclidenoson's superiority compared to placebo and non-inferiority compared to methotrexate in patients with RA. An estimated 90% of RA patients receive methotrexate at some point in their disease. However, studies show that up to 50% of patients stop taking methotrexate due to reasons including drug intolerance, minor and major side effects, and lack of efficacy, creating a significant need for a new, safe and effective treatment option in the RA treatment market.

The randomized, double-blind, active- and placebo-controlled, Phase III study is enrolling patients with clinically active RA who have not been treated with methotrexate. In total, 525 patients will be randomly assigned to one of four groups in a 2:2:2:1 ratio: Piclidenoson 1 mg, Piclidenoson 2 mg, methotrexate, or placebo. The primary efficacy outcome measure is the proportion of patients achieving a Disease Activity Score (DAS) of Low Disease Activity (LDA) at 12 weeks, and efficacy assessments will continue through 24 weeks of treatment.

"With just over half the patients enrolled in this pivotal Phase III study, we have achieved an important milestone and we believe Piclidenoson is a potentially efficacious drug that can be safely used long-term on a daily basis by patients for chronic conditions," stated Can-Fite CEO Dr. Pnina Fishman. "The interim analysis by the IDMC, we believe will facilitate the most efficient use of corporate resources, especially with respect to continuing the current

study and planning our second Phase 3 trial."

Piclidenoson has been out-licensed for the indication of RA in Canada, South Korea, Spain, Austria, Switzerland, Hong Kong, Macau, Taiwan, and China. According to Visiongain, the RA therapeutic market is estimated to reach $47 billion in 2024.

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. It is being evaluated in a Phase III study as a first line treatment, to replace methotrexate, in the treatment of rheumatoid arthritis and a Phase III study in the treatment of 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, 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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. These drugs have an excellent safety profile with experience in over 1,000 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 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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Source: Can-Fite BioPharma Ltd.