

Can-Fite Announces Enrollment of First Patient in its ACRobat Phase III Trial of Piclidenoson in Rheumatoid Arthritis

- **Piclidenoson is being developed as a first line therapy and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis**
- **Rheumatoid Arthritis is forecast to be \$34.6 billion market by 2020**

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 cancer, liver and inflammatory diseases, today announced the first patient has been enrolled and dosed in its Phase III ACRobat trial to evaluate its lead drug candidate, Piclidenoson (CF101), as a first line treatment and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis.

An estimated 90% of rheumatoid arthritis patients receive MTX at some point in their disease. However, studies show that up to 50% of patients stop taking MTX 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 rheumatoid arthritis treatment market which is forecast to reach \$34.6 billion by 2020. Piclidenoson compares favorably with MTX based on an analysis of data from Phase III trials that evaluated MTX in patients with no prior systemic therapy.

The primary endpoint of ACRobat is low disease activity after 12 weeks of treatment in patients dosed with Piclidenoson compared to those dosed with MTX. Piclidenoson at 1 mg and 2 mg, or placebo, will be administered twice daily, and MTX or placebo will be administered once weekly. The total study duration will be 24 weeks in order to provide more data on long term efficacy and safety. This randomized, double-blind, active and placebo-controlled study will enroll approximately 500 patients through clinical sites in Europe, Israel and Canada.

“Dosing the first patient in our Phase III ACRobat trial marks a significant milestone for Can-Fite. We believe Piclidenoson is a potentially superior option to the standard of care, MTX, and we believe that rheumatologists are looking for a safer and more effective alternative,” stated Can-Fite CEO Dr. Pnina Fishman.

About Piclidenoson (CF101)

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 MTX, in the treatment of rheumatoid arthritis. Piclidenoson is also slated to enter a Phase III study in the treatment of moderate-to-severe psoriasis in 2018.

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 inflammatory diseases, cancer, and NAFLD/NASH. The Company's lead drug candidate Piclidenoson is currently being evaluated in a global Phase III trial as a first line therapy for rheumatoid arthritis. Piclidenoson is also slated to enter a Phase III trial for psoriasis in early 2018. Can-Fite's liver cancer drug CF102 concluded patient enrollment in a Phase II study for patients with liver cancer, and it is slated to enter Phase II for the treatment of non-alcoholic steatohepatitis (NASH). CF102 has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 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: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; 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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