

Can Fite Announces the Submission of Safety Reports for Piclidenoson and Namodenoson to FDA and other Regulatory Authorities Showing Favorable Safety Profile

- **The findings allow the continuation of the ongoing Phase II and Phase III clinical studies**
- **The differential effect of the drugs on pathological and normal cells accounts for the favorable 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 cancer, liver and inflammatory diseases, today announced that it has submitted annual safety summaries for 2017 on both Piclidenoson and Namodenoson to regulatory authorities around the world.

The safety reports, known as Development Safety Update Reports (DSURs), are required annually and serve to create timely and transparent communication between drug development sponsors and regulatory agencies. The DSURs summarize safety data from all clinical trials conducted during the year-long reporting period. Can-Fite is pleased to note that both of its molecules under clinical development continue to demonstrate favorable safety profiles in human clinical trials.

In the DSUR for Piclidenoson, Can-Fite notes that there were no deaths, serious adverse events (SAEs), serious adverse reactions (SARs), or suspected unexpected SARs (SUSARs) related to the use of the drug to treat inflammatory diseases during 2017. Furthermore, over the span of development, an estimated 1167 human subjects have received Piclidenoson, without evidence of emerging treatment-limiting toxicities. The Namodenoson development program includes patients with advanced hepatocellular carcinoma (liver cancer), in whom serious adverse events, cancer progression, and mortality are expected and occurred; nevertheless, despite the underlying illness of this population, no SARs or SUSARs were reported during 2017. To date, an estimated 115 human subjects have been dosed with Namodenoson, again without evidence of novel safety concerns.

Both Piclidenoson and Namodenoson target the A3 adenosine receptor, overexpressed in pathological but not in normal body cells. This means that when the drugs enter the body they specifically bind to the diseased but not to the normal cells. This unique drug characteristic is believed to account for the observed favorable safety profile.

The importance of these favorable data allow the Company to continue with the various clinical indications entailing Piclidenoson for the Phase III study in patients with rheumatoid

arthritis and Namodenoson for the Phase II studies in advanced liver cancer and NAFLD/NASH.

Dr. Michael Silverman, Can-Fite's Medical Director, commented: "Can-Fite's Piclidenoson and Namodenoson drugs are unique in today's autoimmune inflammatory, oncology and NASH drugs under development due to their favorable safety profile and the specific anti-inflammatory and anti-cancer effects. We are very happy to continue with our clinical development programs."

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 including rheumatoid arthritis (Phase III ongoing) and psoriasis (completed Phase II/III).

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is being evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug.

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 a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis during 2018. Can-Fite's liver cancer drug, Namodenoson, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and 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: 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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