Can-Fite Granted Patent Allowance for its NASH Drug Namodenoson in South Korea; Results of its NASH Phase II Study are Expected this Quarter

 Can Fite has out licensed Namodenoson for the treatment of NASH to CKD in Korea

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 it has been granted patent allowance in South Korea for its patent titled, "An A3 adenosine receptor ligand for use in treating ectopic fat accumulation" for its drug candidate Namodenoson. The main claim among others is the ability of Namodenoson to improve non-alcoholic steatohepatitis (NASH) accompanied by fibrosis.

Chong Kun Dang Pharmaceuticals (CKD) (Korean Stock Exchange: 185750.KS) of South Korea, has licensed the distribution rights to Namodenoson in South Korea for the treatment of liver cancer and NASH in a deal totaling \$6 million in upfront and milestone payments, plus a transfer price for delivering finished products to CKD. The Company has received \$2 million from CKD to date for Namodenoson in the treatment of liver cancer and NASH.

Can Fite plans to release data from its Phase II study of Namodenoson in NASH patients during this quarter. The multicenter, randomized, double-blinded, placebo-controlled, dose-finding efficacy and safety study has enrolled 60 patients with NAFLD (non-alcoholic fatty liver disease) with or without NASH. Patients who suffer from NAFLD/NASH with evidence of active inflammation are treated twice daily with 12.5 mg or 25 mg of oral Namodenoson, or placebo for 12 weeks. The primary endpoint of the Phase II study is the anti-inflammatory effect of the drug, as determined by mean percent change from baseline in ALT blood levels and safety. Secondary endpoints include percentage change from baseline of liver fat, as measured by MRI-PDFF (proton density fat fraction).

"The notice of allowance for this patent application secures Can-Fite's proprietary rights in a commercially very important country, South Korea, for an indication where there is a high market need", said Dr. Pnina Fishman, the Company's CEO. "We look forward to reporting our topline results during this quarter.

Namodenoson has been also out-licensed for the indication of NASH in China. There is currently no U.S. FDA approved drug for the treatment of NASH, which is an addressable pharmaceutical market estimated to reach \$35-40 billion by 2025.

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 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 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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