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Can-Fite Broadens its Strong Intellectual Property (IP) for NASH: Received Patent Allowance in Canada

Patent has already been issued in other major markets including the U.S., EU, Japan and China

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced it received a Notice of Allowance from the Canadian Intellectual Property Office for its patent application titled “An A3 Adenosine Receptor Ligand For Use In Treating Ectopic Fat Accumulation”. This invention addresses the use of Namodenoson for the reduction of liver fat in patients with NASH a clinical indication that is being developed by Can-Fite. In a successfully concluded Phase IIa study, Namodenoson, one of the Company’s two drugs in advanced clinical development, reduced liver fat content, showed anti-inflammatory effects manifested by a significant decrease in the liver enzymes ALT & AST, and decreased body weight in patients with NASH. A Company-sponsored study for Namodenoson for this indication is currently enrolling patients for a Phase IIb study which will include 140 patients, in whom liver pathology is the primary endpoint.

Can-Fite’s Namodenoson, is currently out-licensed for the treatment of NASH to the Swiss company Ewopharma for territories in Eastern Europe, to CMS China for the territories of China, HK and Macau, and to the South Korean company CKD for the territory of South Korea. The Company also has a distribution agreement in Canada for its anti-inflammatory drug, Piclidenoson, for the treatment of psoriasis.

“This additional patent in Canada for fatty liver disease adds to our growing IP estate for this high-value indication of the Namodenoson drug candidate. Our strong and broad IP, together with the positive data from the Phase IIa and the drug safety, position it as a promising candidate for the treatment of this liver disease,” stated Dr. Ilan Cohn, Can-Fite founder, a recognized business development expert in the medical arena, and also a leading Israeli patent attorney and Partner & co-Founder of Cohn, de Vries, Stadler & Co, Patent and Trademark Attorneys.

The NASH market is expected to reach $24 billion by 2028. According to the American Liver Foundation, between 30-40% of adults in the U.S. have non-alcoholic fatty liver disease, one of the most common causes of liver disease in the U.S. Non-alcoholic steatohepatitis affects up to 5% of Americans, or up to 16 million people and is expected to be most frequent reason for liver transplants in the U.S. by 2030.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is currently being evaluated in a pivotal

Phase III trial for advanced liver cancer, a Phase IIb trial for the treatment of steatotic liver disease (SLD), and the Company is planning a Phase IIa study in pancreatic cancer. A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential expression may be one of the important factors that accounts for the excellent safety profile of the drug.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF) is an advanced clinical stage drug development Company with a platform technology that addresses multi-billion dollar markets in the treatment of cancer, liver, and inflammatory disease. One of the two Company's lead drug candidates, Piclidenoson recently reported positive topline results in a Phase III trial for psoriasis. A pivotal Phase III for this drug is expected to commence soon. Can-Fite's other lead drug for treating cancer and liver diseases, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of steatotic liver disease (SLD), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic cancer. Namodenoson has been granted Orphan Drug Designation in the U.S. and Europe for its HCC indication 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. Piclidenoson and Namodenoson have an excellent safety profile with experience in over 1,600 patients in clinical studies to date. For more information please visit: www.canfite.com.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, 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; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the “Risk Factors” section of Can-Fite’s Annual Report on Form 20-F filed with the SEC on March 30, 2023 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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