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# Can-Fite: Namodenoson's Treatment of Liver Fibrosis Receives Notice of Allowance from U.S. Patent Office

***Broad patent addresses markets for the treatment of all advanced liver fibrosis indications***

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 inflammatory, cancer and liver diseases, today announced it has received a Notice of Allowance from the U.S. Patent and Trademark Office (PTO) for its invention titled "Method for Treating Fibrotic Liver Tissue Using CL-IB MECA".

Currently, Namodenoson (CL-IB-MECA) is being developed for two liver indications, liver cancer and NASH. The allowance granted by the US PTO opens the door for much broader market needs which entail all clinical conditions with advanced liver fibrosis including autoimmune hepatitis, primary biliary cirrhosis (PBC), nonalcoholic fatty liver disease (NAFLD), and alcoholic liver disease (ALD) among others. The global liver disease treatment market was valued at approximately [\\$20 billion](#) in 2020 by Allied Market Research.

Can-Fite is currently enrolling patients in a Phase IIb trial of Namodenoson for the treatment of NASH, an advanced non-alcoholic fatty liver disease, for which there is no U.S. FDA approved treatment. Additionally, the Company expects to commence enrollment in a pivotal Phase III study of Namodenoson in the treatment of advanced liver cancer (hepatocellular carcinoma CPB7).

Can-Fite's robust IP portfolio includes patents that address NASH and liver cancer, issued in approximately 40 countries. Namodenoson has been out-licensed in select countries for the treatment of NASH and liver cancer with agreements that include upfront and milestone payments.

"This U.S. patent is a very important addition to our growing IP portfolio in liver diseases. It is very well timed with our Phase IIb NASH study and Phase III liver cancer trial. Both are high value indications in which our robust patent portfolio and Namodenoson's safety and efficacy profile position Can-Fite for potential additional strategic distribution deals worldwide," stated Can-Fite CEO Dr. Pnina Fishman.

## About NASH

There is currently no U.S. FDA approved treatment for NASH, an addressable pharmaceutical market estimated to reach \$35-\$40 billion by 2025 driven by increasing incidence. The U.S. National Institutes of Health estimate the prevalence of NASH in the U.S. at 2-5% of the population. NASH is the leading cause for liver transplants among women and second leading cause overall in the U.S. Given the rate of increase, it is expected to become the leading indication for liver transplants in males as well.

## **About HCC**

Hepatocellular carcinoma (HCC) is the most common form of liver cancer. HCC with underlying Child Pugh B7 (CPB7) is one of the most advanced forms of liver cancer. More than 800,000 people are diagnosed with liver cancer annually and approximately 700,000 die of the disease each year, according to the [American Cancer Society](#). The HCC drug market is projected to reach \$3.8 billion by 2027.

## **About Namodenoson**

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was 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, liver, and inflammatory disease. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and a Phase IIb 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. These drugs have an excellent safety profile with experience in over 1,500 patients in clinical studies to date. For more information please visit: [www.can-fite.com](http://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 impact of the COVID-19 pandemic; 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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