

# Can-Fite Completes Patient Enrolment for its Phase II Study of Namodenoson in the Treatment of Liver Cancer

- ***Namodenoson has been granted Orphan Drug Designation in Europe and the U.S. and Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma (HCC)***
- ***Based on the clear unmet medical need for HCC patients with Child-Pugh Class B cirrhosis, management believes success in the current trial will position Namodenoson for rapid progress towards registration***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, today announced that the Phase II liver cancer clinical trial for Namodenoson (CF102), a novel compound for the treatment of advanced hepatocellular carcinoma (HCC), has successfully enrolled and randomized all 78 patients planned in the clinical trial protocol.

“There is definitely a large unmet medical need for the patient population represented in our trial. These are patients who have not responded to first-line therapy with the current standard of care and experienced further disease progression, in addition to having underlying Child-Pugh Class B cirrhosis. In view of the unique nature of our target population, along with our orphan and fast track status, we believe that success in the current Phase II trial will position us for rapid progress towards registration,” stated Can-Fite Medical Director, Dr. Michael Silverman. “We now look forward to confirming the encouraging Phase I/II results, which will pave the way for Can-Fite to bring a new treatment option to patients with advanced liver cancer.”

The global Phase II study is being conducted in the U.S., Europe and Israel. Patients with advanced HCC, Child Pugh B, are treated twice daily with 25 mg of oral Namodenoson, the dose found to be the most efficacious in Can-Fite's earlier Phase I/II study. The primary endpoint of the Phase II study is Overall Survival (OS). Secondary endpoints include Progression Free Survival (PFS), safety, and the relationship between outcomes and A3AR expression. As is standard in this indication, the primary endpoint of OS requires following the entire patient population until the statistically predetermined number of events occur. Can-Fite is following the survival data closely and will perform the survival analysis at the earliest possible opportunity.

Can-Fite's prior Phase I/II study of Namodenoson in this indication successfully achieved its primary and secondary endpoints, with a good safety profile. Most of the patients enrolled in the Phase I/II study had failed prior treatment with Nexavar® (sorafenib), the only drug currently approved for this indication.

Data also showed that Namodenoson has a liver protective effect that is very unique

compared to Nexavar® and other drugs under development for HCC which have shown to induce hepato-toxicity.

According to Datamonitor, the market for hepatocellular carcinoma drugs is projected to reach \$1.4 billion in 2019. Nexavar® annual sales, as reported by Bayer, were €870 million in 2016.

#### 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. Can-Fite has received Orphan Drug Designation for Namodenoson in Europe and the U.S., as well as Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma.

#### About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: 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 scheduled to enter a Phase III trial for rheumatoid arthritis in 2017 and a Phase III trial for psoriasis in early 2018. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug Namodenoson is in Phase II trials for patients with liver cancer and is slated to enter Phase II 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 hepatocellular carcinoma 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 is being prepared for an IND submission to the FDA and a Phase I trial. 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](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: 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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Source: Can-Fite BioPharma Ltd.