

# Top Line Results of the Namodenoson Phase II Advanced Liver Cancer Trial Expected by End of Year

- **Namodenoson seeks to address a major unmet need for Child Pugh B patients with advanced liver cancer**
- **Namodenoson has received Fast Track Status in the U.S. and Orphan Drug Designation in Europe and the U.S.**

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 provided an update on its Phase II clinical trial of drug candidate Namodenoson (CF102) for the treatment of advanced hepatocellular carcinoma (HCC) in patients whose disease has progressed on sorafenib therapy. Top line efficacy results are expected by end of year.

The global Phase II study is being conducted in the U.S., Europe and Israel. Patients with advanced HCC, Child Pugh B, who failed Nexavar (sorafenib) as a first line treatment are treated twice daily with 25 mg of oral Namodenoson or placebo using a 2:1 randomization. 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.

Advanced liver cancer is categorized into 3 subclasses including Child Pugh A, mostly treated with Nexavar, Child Pugh B and Child Pugh C. Although a few drugs for the treatment of advanced liver cancer have recently launched, none are specifically aimed at treating patients who have reached the Child Pugh B stage. This represents a major unmet need and potentially positions Namodenoson as an important drug candidate to treat this patient population.

Enrollment of 78 patients was completed in August 2017. While the trial continues treating subjects in a blinded fashion (either Namodenoson 25 mg BID or matching placebo), Can-Fite notes that of the 78 subjects originally enrolled, 22 completed at least 12 cycles of treatment (each cycle is 28 days of treatment), of whom 5 completed 24 cycles. The longest-treated subject has been receiving study medication for over 3 years.

Accumulated safety data to date continues to indicate a favorable safety profile, with no clinically significant novel or emerging events attributed to chronic treatment with Namodenoson.

Can-Fite' CEO, Dr. Pnina Fishman, commented, "We are pleased with the progress so far in our clinical trial for Namodenoson for the treatment of advanced HCC, the third leading cause of cancer deaths worldwide, and look forward to data release. We believe a major advantage of Namodenoson stems from its favorable safety profile demonstrated thus far, in

which Namodenoson selectively targets diseased cells while sparing normal cells which express very low levels of the A3 receptor.

Can-Fite 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 HCC.

### **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 Phase III trials for rheumatoid arthritis and psoriasis. 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](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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