September 2, 2026

Can-Fite Reports Longer-Than-Anticipated Overall Survival in Ongoing Pivotal Phase III Liver Cancer Study

Company plans to advance the interim analysis of its Phase III Namodenoson study in advanced hepatocellular carcinoma

Ramat Gan, Israel, Sept. 02, 2026 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a clinical-stage biotechnology company developing a pipeline of proprietary small molecule drugs targeting oncological and inflammatory diseases, today announced that blinded overall survival observed across the entire patient population in its ongoing pivotal Phase III study of Namodenoson in advanced hepatocellular carcinoma (HCC) appears longer than originally anticipated based on the assumptions underlying the study design.

The pivotal Phase III study is a randomized, double-blind, placebo-controlled study evaluating Namodenoson in patients with advanced HCC and underlying Child-Pugh B7 cirrhosis. Patients are randomized 2:1 to receive Namodenoson or placebo, with overall survival as the primary efficacy endpoint. The observed survival reflects the pooled, blinded study population and includes patients receiving both Namodenoson and placebo. Accordingly, no conclusions regarding treatment efficacy or differences between the study arms can be drawn from these data at this stage.

In view of the longer-than-anticipated survival observed in the study population, Can-Fite is evaluating an earlier timing for the study's planned interim analysis. The interim analysis will enable an independent assessment of overall survival between the Namodenoson and placebo treatment groups in accordance with the study's statistical analysis plan and applicable regulatory requirements.

"We are encouraged by the longer overall survival being observed among patients participating in this pivotal study," said Motti Farbstein Can-Fite CEO & CFO. "While the study remains blinded and these observations cannot predict the treatment effect of Namodenoson, we believe that conducting the planned interim analysis earlier could provide important information regarding the potential clinical benefit of Namodenoson in this patient population with substantial unmet medical need."

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 3 trial for advanced liver cancer, concluded successfully a Phase 2a study in pancreatic cancer and is enrolling patients in a Phase 2b trial for the treatment of Metabolic Dysfunction-associated Steatohepatitis (MASH). 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 is designed to address multi-billion dollar markets in the treatment of cancer, liver, and inflammatory disease. The Company's lead drug candidate, Piclidenoson recently reported topline results in a Phase 3 trial for psoriasis and commenced a pivotal Phase 3 trial. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase 2b trial for the treatment of MASH, and in a Phase 2a study in pancreatic cancer. 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 1,600 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 and plans to accelerate its interim analysis of its Phase III trial of Namodenoson for HCC. 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 market and other conditions, 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 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 26, 2026 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.

Contact

Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

Source: Can-Fite BioPharma Ltd.