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Can-Fite Highlights Advanced FDA and EMA Regulatory Status of its Phase III Drug Candidates

Namodenoson Holds FDA Fast Track and U.S. and European Orphan Drug Designations; Piclidenoson and Namodenoson Are Advancing in Phase III Programs

Ramat Gan, Israel, Aug. 12, 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 provided an update on the regulatory status of its two lead drug candidates, Piclidenoson and Namodenoson. Both drug candidates are being advanced in Phase III clinical development programs under regulatory frameworks established with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), providing defined regulatory pathways toward potential marketing approval.

Namodenoson, Can-Fite's orally administered A3 adenosine receptor (A3AR) agonist, is currently being evaluated in a pivotal Phase III study for the treatment of patients with advanced liver cancer, hepatocellular carcinoma (HCC) and underlying Child-Pugh B7 liver cirrhosis. The Phase III study is being conducted under regulatory guidance from both the FDA and EMA and is designed to support potential marketing authorization applications in the United States and Europe, if the study meets its predefined efficacy and safety endpoints.

Piclidenoson, Can-Fite's oral A3AR agonist for inflammatory diseases, is currently being evaluated in a Phase III clinical program for the treatment of moderate-to-severe plaque psoriasis.

Can-Fite's clinical development strategy is focused on advancing its lead drug candidates through late-stage clinical development under regulatory pathways established with leading regulatory authorities.

Namodenoson's FDA **Fast Track** and FDA and EMA **Orphan Drug** designations provide additional regulatory advantages as the Company advances its pivotal HCC program, while Piclidenoson is progressing through Phase III development in psoriasis.

Can-Fite believes that the advanced regulatory status of both programs significantly strengthens the Company's late-stage clinical pipeline and provides a clear framework for advancing Piclidenoson and Namodenoson toward potential regulatory submissions and commercialization.

"Can-Fite has reached an important stage in its development, with both of our lead drug candidates in Phase III programs and with established regulatory pathways in the United States and Europe," stated Dr. Pnina Fishman, Can-Fite's Chief Scientific Officer and Executive Chairperson. "Namodenoson's Fast Track and Orphan Drug designations,

together with our ongoing pivotal Phase III HCC study, and the Phase III development of Piclidenoson in psoriasis, demonstrate the maturity of our clinical pipeline. We believe these regulatory achievements provide greater clarity regarding the development and potential approval pathways for our drug candidates and bring us closer to our goal of delivering new oral therapies to patients with significant unmet medical needs."

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, the Company's development programs, regulatory status, and potential approval pathways.. 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.

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