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Can-Fite Provides Update on Clinical and Financial Status

RAMAT GAN, Israel, Dec. 16, 2025 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small-molecule drugs targeting oncological and inflammatory diseases, today announced an update on its clinical development activities and financial status.

Namodenoson drug candidate: Can-Fite is currently enrolling patients in a pivotal Phase III clinical study evaluating Namodenoson for the treatment of advanced hepatocellular carcinoma (HCC) in patients with Child-Pugh B7 liver function. This patient population represents a significant unmet medical need, as no approved therapies are currently available. An interim analysis from the Phase III study is expected to be in approximately Q4 2026. Subject to positive interim results, the Company may be eligible to seek conditional regulatory approval from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

In parallel, Can-Fite is enrolling patients in a Phase IIb clinical study of Namodenoson for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). This study follows positive results from a completed Phase IIa trial, which demonstrated anti-inflammatory, anti-steatotic, and anti-fibrotic effects, with data published in peer-reviewed literature.

In addition, Namodenoson is being evaluated in a Phase IIa clinical study in patients with pancreatic cancer who have failed first-line treatment. Patient enrollment in this study is nearing completion, and the Company expects to report data during the second quarter of 2026.

Piclidenoson drug candidate: Can-Fite is currently enrolling patients in a pivotal Phase III clinical study for the treatment of psoriasis. In this study, patients receive Piclidenoson orally, administered twice daily. The primary efficacy endpoints of the trial are PASI 75 (Psoriasis Area and Severity Index) and Physician's Global Assessment (PGA), consistent with regulatory guidance for late-stage psoriasis studies. Based on the Company's current assumptions, interim analysis data is expected to be released in the second quarter of 2026. The Company also completed the development of a Phase II study protocol for the rare genetic disease Lowe Syndrome and plans to submit it to regulatory authorities in Italy and EMA during Q1 2026.

Cash and cash equivalents: As of June 30, 2025, Can-Fite had cash and cash equivalents and short term deposits of $6.45 million. On July 28, 2025, Can-Fite completed a public offering for aggregate gross proceeds of $5 million. In November 2025 Can-Fite Raised $2.2M through its ATM facility.

"Our advancing clinical programs reflect Can-Fite's focused strategy of addressing significant unmet medical needs with orally administered, well-characterized drug candidates," said Motti Farbstein, Chief Executive Officer of Can-Fite BioPharma. "With pivotal Phase III studies ongoing in liver cancer and psoriasis, alongside progressing mid-stage programs in

MASH and pancreatic cancer, we believe we are well positioned to generate meaningful clinical data over the coming quarters while maintaining disciplined execution."

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 reported topline results in a Phase III trial for psoriasis and commenced a pivotal Phase III trial. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in a Phase IIa 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: https://www.canfite.com/.

Forward-Looking Statements

This press release contains forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts and expectations with respect to the timing of release of data and regulatory submissions. 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 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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 April 7, 2025 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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