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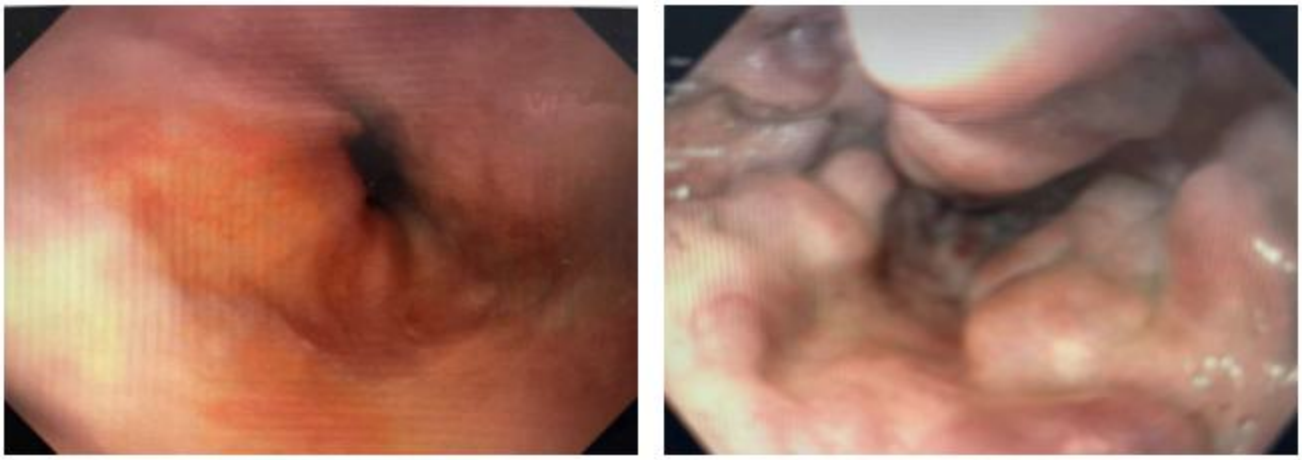
Can-Fite Reports Complete Resolution of Esophageal Varices in Decompensated Cirrhosis Patient Treated with Namodenoson

Ramat Gan, Israel, Sept. 15, 2025 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company developing a pipeline of proprietary small molecule drugs targeting oncological and inflammatory diseases, today announced a significant new clinical finding under its compassionate use program in decompensated liver cirrhosis. The patient, previously reported by Can-Fite to have experienced the disappearance of end-stage liver disease complications while receiving Namodenoson, has now demonstrated a complete resolution of esophageal varices, as confirmed by endoscopic evaluation.

Esophageal varices are a common and severe complication of advanced liver disease, associated with a high risk of life-threatening gastrointestinal bleeding. Their resolution in a patient with decompensated cirrhosis is an uncommon clinical outcome and may suggest a disease-modifying effect of Namodenoson.

“This case highlights the potential of Namodenoson to address life-threatening complications of advanced liver disease,” stated Prof. Ohad Etzion, Chief of Gastroenterology and Liver Diseases at Soroka Medical Center in Israel. “We are encouraged by these findings, which may provide important insights for Namodenoson’s ongoing clinical development.”

Endoscopic images of the patient’s esophagus before and after Namodenoson treatment (see below) demonstrate the disappearance of varices under compassionate use therapy.



Namodenoson is currently being evaluated in a Phase III clinical trial for the treatment of hepatocellular carcinoma (HCC) in patients with advanced liver disease (Child-Pugh B). Data from compassionate use cases may provide valuable supplementary evidence

regarding its broader therapeutic potential.

In 2017, an estimated 10.6 million people globally were affected by decompensated cirrhosis, and the available treatment options remain scarce, especially for patients who have reached the advanced stages of the disease. Highlighting the urgent need for new therapies, the American Liver Foundation has stated that there are more patients in need of a liver transplant than available organs, with some patients waiting over five years for a transplant. The U.S. market for liver cirrhosis treatment is projected to grow to approximately $15 billion by 2030.

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 III trial for advanced liver cancer, a Phase IIb trial for the treatment of Metabolic Dysfunction-associated Steatohepatitis (MASH), and in a Phase IIa study in pancreatic cancer. 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 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 may contain forward-looking statements, about Can-Fite’s expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. 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 March 28, 2024 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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