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Improvement in Patient with Decompensated Liver Cirrhosis Upon Treatment with Namodenoson

Liver cirrhosis treatment global market is estimated to reach $29.2 billion by 2030

Ramat Gan, Israel, July 01, 2024 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, announced today that a patient with liver decompensated cirrhosis who was treated with Namodenoson at the Soroka Medical Center in Israel under compassionate use showed an improvement in liver indices. This drug candidate is currently used in a pivotal Phase III study for patients with advanced liver cancer and a Phase IIb study for MASH (metabolic dysfunction-associated steatohepatitis).

Decompensated cirrhosis is defined as an acute deterioration in liver function in a patient with cirrhosis and is characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome, or variceal hemorrhage. While some drugs can treat symptoms, there is no therapeutic approach that has shown efficacy in slowing disease progression.

In the past year Can-Fite has initiated a compassionate use program at the Soroka Medical Center, Beersheva, Israel, for the treatment of decompensated patients with Namodenoson. The first patient, a 63-year-old female with a history of decompensated primary biliary cirrhosis is now treated for one year with Namodenoson. Prior to the treatment with Namodenoson and despite best medical care for her underlying disease, she developed ascites and was admitted to the hospital with acute variceal bleeding. Currently, the patient shows improvement in liver function tests hematological parameters and FibroScan values and has not experienced any event of decompensation since starting treatment with Namodenoson. Namodenoson is known to induce liver protective effects in other liver pathologies, and Phase IIa data in patients suffering from MASH (metabolic dysfunction-associated steatohepatitis), responded positively to the drug, showing anti-inflammatory, anti-steatotic, and antifibrotic effects with a very favorable safety profile.

Ohad Etzion, MD, Director, Department of Gastroenterology and Liver Diseases at the Soroka Medical Center, Beer Sheva, Israel, the Investigator and Initiator of this study commented, “We were very much encouraged by the response of the first patient with decompensated liver cirrhosis who showed a rapid and sustained response to the drug with an improvement with liver indices. We plan to treat more patients and hopefully see an improvement of liver function in this devastating disease.

Decompensated cirrhosis is defined as an acute deterioration in liver function, with cirrhosis and is characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome, or variceal hemorrhage. While some drugs can treat symptoms, there is no therapeutic approach that has shown efficacy in slowing disease progression. An estimated 10.6 million people globally had decompensated cirrhosis in 2017, with few treatment options available

aside from liver transplants if the decompensated cirrhosis has reached an advanced stage. Underscoring the need for an effective treatment, the American Liver Foundation states there are more people who need a liver than supply available, and some people can be on the wait list for a liver transplant for more than 5 years. The treatment of liver cirrhosis globally is estimated to become an approximately $29.2 billion market by 2031.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for Metabolic Dysfunction-Associated Steatohepatitis (MASH). 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: 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 III trial for psoriasis and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of Metabolic Dysfunction-associated Steatohepatitis (MASH), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning 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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