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Can-Fite BioPharma Announces New Pre-Clinical Data Supporting a Novel Anti-NASH Mechanism of Action for Namodenoson

- **Pre-clinical studies show Namodenoson's mechanism of action in inhibiting inflammation and fibrosis in NASH models**
- **Can-Fite initiated lately patient enrollment for Phase II NAFLD/NASH Study with Namodenoson**

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address liver and inflammatory diseases, announced today that pre-clinical studies show Namodenoson's novel mechanism of action which entails de-regulation of 3 key signaling pathways which mediate the etiology and pathology of NAFLD/NASH and are responsible for the anti-inflammatory and anti-fibrogenic effect in the liver.

Pre-clinical studies were conducted in hepato-stellate cells *in vitro* and in an experimental NASH CCL4 model, showing that in both systems, the molecular mechanism of action of Namodenoson was conferred by decreased expression levels of the signaling protein phosphoinositol-3-phosphate (PI3K) which controls 3 downstream signal transduction pathways, the Wnt, NF-kB and α-SMA, which control liver inflammation and liver fibrosis. The detailed data is scheduled to be presented at the 2018 International Liver Congress (ILC), which is the annual meeting of the European Association for the Study of the Liver (EASL) (http://www.easl.eu/discover/events/detail/2018/the-international-liver-congress-2018).

The Company is currently conducting a Phase II trial with its drug candidate Namodenoson for the treatment of 60 patients with non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). There is currently no U.S. FDA approved drug for the treatment of NASH, which is an addressable pharmaceutical market estimated to reach $35-40 billion by 2025. Can-Fite's 12-week study has been designed by leading Key Opinion Leaders in the area of NASH and liver diseases in the US including the company CAB members, Dr. Scott Friedman, Chief of the Division of Liver Diseases at the Icahn School of Medicine at Mount Sinai in New York; Dr. Arun Sanayal, Professor of Medicine, Physiology and Molecular Pathology at Virginia Commonwealth University School of Medicine; Dr. Rifaat Safadi, Head of the Liver Unit, Gastroenterology and Liver Diseases, Division of Medicine at Hadassah Medical Center and Dr. Stephen A. Harrison, the Medical Director of Pinnacle Clinical Research.

Namodenoson has been tested in over 100 subjects with other liver diseases, with clinical data suggesting a very favorable safety profile.

“We believe that the anti-inflammatory and anti-fibrogenic effects of Namodenoson, together with the favorable safety profile to date make it a promising drug candidate for the treatment of NAFLD/NASH,” stated Prof. Rifaat Safadi.

About NAFLD/NASH

NAFLD is characterized by excess fat accumulation in the form of triglycerides (steatosis) in the liver. According to a study published in Hepatology, an estimated 17%-33% of the population in the U.S. has NAFLD, with a higher prevalence in people with type II diabetes. Incidence is increasing based on rising obesity rates. NAFLD includes a range of liver diseases, with NASH being the more advanced form, manifesting as hepatic injury and inflammation. According to the NIH, the incidence of NASH in the U.S. is believed to affect 2-5% of the population. The spectrum of NAFLDs resembles alcoholic liver disease; however, they occur in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer. By 2025, the addressable pharmaceutical market for NASH is estimated to reach $35-40 billion.

About Namodenoson (CF102)

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is being evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential effect is believed to account for the excellent safety profile of the drug. Can-Fite has received Orphan Drug Designation for Namodenoson in Europe and the U.S., as well as Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CFBI) 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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis in early 2018. Can-Fite's liver cancer drug, Namodenoson, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and for the treatment of non-alcoholic steatohepatitis (NASH). 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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. These drugs have an excellent safety profile with experience in over 1,000 patients in clinical studies to date. For more information please visit: www.can-fite.com.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, market risks and uncertainties, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. 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. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. 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 risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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