November 23, 2015

Can-Fite Announces Compelling Pre-Clinical Data on CF102 in the Treatment of Non-Alcoholic Steatohepatitis (NASH)

- Files patent for CF102 in the treatment of NASH

- Large unmet need for 2-5% of U.S. population living with NASH

- Estimated $35-40 billion market by 2025

- No FDA approved therapies currently exist

PETACH TIKVA, Israel, Nov. 23, 2015 /PRNewswire/ -- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory diseases, cancer, and sexual dysfunction, today announced development of its drug candidate CF102, which is currently in Phase II trials for hepatocellular carcinoma (HCC) the most common form of liver cancer, will be expanded into treatment for non-alcoholic steatohepatitis (NASH).

NASH is characterized by excess fat in the liver along with inflammation and liver damage. It resembles alcoholic liver disease; however, it occurs in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer. According to the National Institutes of Health, NASH affects between 2% and 5% of Americans and the prevalence of NASH has been increasing, potentially due to increasing rates of obesity and diabetes. By 2025, Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach $35-40 billion in size. As of today, while there are several companies developing drugs to treat NASH that are in preclinical and clinical development, no specific U.S. Food and Drug Administration (FDA) approved treatment for NASH exists.

"Results from our recently concluded preclinical study of CF102 in liver disease revealed compelling data. Based on these findings, we've filed a patent for CF102 in the treatment of NASH," stated Can-Fite CEO Dr. Pnina Fishman. "Because the prevalence of NASH continues to grow and no treatment currently exists, our data support the development of CF102 for the treatment of NASH."

CF102 revealed its capability to improve liver pathology in a NAFLD (non-alcoholic fatty liver disease)/diabetes animal model of NASH. The data showed:

- CF102 had a statistically significant reduction in NAFLD activity score compared to placebo.
- CF102 reduced liver-to-body weight compared to placebo.
- Representative photomicrographs of H&E-stained liver sections showed improved pathology in animals receiving CF102 vs. placebo.
- CF102 decreased plasma ALT and triglycerides levels in the livers of NASH-model

compared to placebo.
- Liver sections from the placebo group exhibited severe micro- and macrovesicular fat deposits, hepatocellular ballooning and inflammatory cell infiltration, whereas the CF102 treated group showed a significant decrease in steatosis, ballooning and lobular inflammation compared to the placebo group.

In prior preclinical studies, CF102 has shown efficacy in the treatment of liver regeneration and function following liver surgery.

Can-Fite currently has a U.S. Investigational New Drug (IND) application active with the U.S. FDA for CF102. CF102 is currently being evaluated as a second-line treatment for HCC through a global Phase II trial. Can-Fite has received Orphan Drugs Designation for CF102 for this indication in Europe and the U.S., as well as Fast Track Status in the U.S. Data from the Phase II HCC study is expected in 2016.

About CF102

CF102 is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). A3AR is highly expressed in tumor cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug. In Can-Fite's pre-clinical and clinical studies, CF102 has demonstrated a robust anti-tumor effect via deregulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: 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 is preparing for a Phase III CF101 trial for rheumatoid arthritis and is preparing its protocol for its next advanced psoriasis clinical trial. Can-Fite's liver cancer drug CF102 is in Phase II trials and has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. The Company's CF602 has shown efficacy in the treatment of erectile dysfunction. Can-Fite has initiated a full pre-clinical program for CF602 in preparation for filing an IND with the U.S. FDA in this indication. These drugs have an excellent safety profile with experience in over 1,200 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, 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

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