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U.S. Food and Drug Administration Grants Fast Track Designation to Can-Fite's CF102 in the Treatment of Liver Cancer

- Global market for liver cancer drugs is projected to exceed \$2 billion in 2015

PETACH TIKVA, Israel, Sept. 17, 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 and cancer diseases, today announced the U.S. Food and Drug Administration (FDA) has granted the Company's drug candidate CF102 Fast Track designation as a second line treatment for hepatocellular carcinoma (HCC), the most common form of liver cancer. CF102 had already received the FDA's Orphan Drug designation.

Can-Fite is currently conducting a Phase II study for this indication in the U.S., Europe and Israel. The randomized, double blind, placebo controlled study is expected to complete enrollment by the end of the first half of 2016 in 78 patients with Child-Pugh Class B cirrhosis who failed the only FDA approved drug on the market, Nexavar® (sorafenib). Patients are treated twice daily with 25 mg of oral CF102, which has been found to be the most efficacious dose in Can-Fite's earlier Phase I/II study resulting in the longest overall survival time, with excellent safety results.

[Fast Track](#), aimed at getting important new drugs that meet an unmet need to patients earlier, is expected to expedite the development of CF102. Drugs that receive Fast Track designation benefit from more frequent meetings and communications with the FDA to review the drug's development plan to support approval. It also allows the Company to submit parts of the New Drug Application (NDA) on a rolling basis for review as data becomes available. Since the Fast Track Program started, from March 1998 through June 30, 2015 a total of [318 Fast Track applications have been received](#) by the FDA. The FDA has granted 202 of them, and denied 110, with 6 more pending.

"We are very pleased that the FDA recognizes the potential for CF102 to treat HCC patients who have tried, and not been responsive to Nexavar, the only FDA approved drug currently on the market for this indication," stated Can-Fite CEO Dr. Pnina Fishman. "We consider Fast Track designation to be a major catalyst for our CF102 development program and we believe it could shorten our time to market for CF102, thereby making a considerable difference for patients."

According to Global Industry Analysts, the global market for liver cancer drugs is projected to exceed \$2 billion in 2015. Nexavar® annual sales, as reported by Bayer, were €773 million in 2014.

[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 and Fast Track Designation 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 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, including, but not limited to, the factors summarized 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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