

October 12, 2015

European Medicines Agency Grants Orphan Designation to Can-Fite's CF102 in the Treatment of Liver Cancer

10-year market exclusivity in Europe following marketing authorization in 31 European Economic Area (EEA) countries

PETACH TIKVA, Israel, Oct. 12, 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 Company's oncology drug candidate, CF102, has been granted [Orphan Drug Designation](#) by the European Medicines Agency (EMA) for the indication of hepatocellular carcinoma (HCC), the most common form of liver cancer.

CF102 will benefit from protocol assistance and a 10-year market exclusivity following market authorization [in](#) the 28 European Union (EU) Member states, as well as 3 additional European Economic Area (EEA) countries.

"The EMA's Orphan Drug designation for CF102 is the latest in a series of catalysts that we believe are accelerating the clinical development path of our liver cancer drug towards market approval. As we actively recruit patients in our Phase II study of CF102 in Europe, we are pleased the EMA will support CF102 through protocol assistance and post-authorization market exclusivity," stated Can-Fite CEO Dr. Pnina Fishman.

In the U.S., CF102 has already received Fast Track Designation as a second line for the treatment of HCC of patients who have previously received Nexavar (sorafenib) and Orphan Drug Designation for the treatment of HCC. Israel's Ministry of Health has also approved CF102 for Compassionate Use for HCC.

Can-Fite is conducting a Phase II study with CF102 in patients with advanced HCC 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.

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 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 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.

Contact

Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/european-medicines-agency-grants-orphan-designation-to-can-fites-cf102-in-the-treatment-of-liver-cancer-300157647.html>

SOURCE Can-Fite BioPharma Ltd.