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Can-Fite Announces Upcoming 2015 Clinical Milestones for its Pipeline of Drugs in 4 Indications

PETACH TIKVA, Israel, Jan. 6, 2015 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer and inflammatory diseases, today announced its anticipated clinical milestones for calendar 2015.

"We are looking forward to a very active year in terms of clinical developments and release of data from key trials including late stage studies for psoriasis," stated Can-Fite CEO Dr. Pnina Fishman.

Q1 2015 Data release from Phase II/III psoriasis trial

In the first quarter of 2015, Can-Fite plans to announce top line results from its Phase II/III trial of its lead drug candidate CF101 in the treatment of psoriasis. The Company completed enrollment of over 300 patients at 17 clinical centers in the U.S., Europe, and Israel. Previously announced interim results for the first 100 patients were positive. The psoriasis therapeutic market was worth \$3.6 billion in 2010 and is forecast to grow to \$6.7 billion by 2018, according to estimates of GlobalData.

Q1 2015 Completion of commercial A3AR biomarker blood test kit

In the first quarter of 2015, Can-Fite anticipates completion of its biomarker blood test kit for the A3 adenosine receptor (A3AR) as a biomarker to predict patient's response to CF101. The kit is designed to test A3AR expression levels prior to treatment with CF101, thereby predicting a patient's response to the drug and providing more personalized medicine. The U.S. Patent and Trademark Office issued Can-Fite a patent for the utilization of A3AR as a biomarker to predict patients' response to CF101 in all autoimmune inflammatory indications.

H2 2015 Data release from analysis of Phase II glaucoma trial

During the first half of 2015, Can-Fite expects to announce results from its Phase II study of CF101 in the treatment of glaucoma. The 88 patient study is planned to be conducted in two European countries by Can-Fite's subsidiary OphthaliX Inc. (OTCQB: OPLI). The global glaucoma market was estimated by GlobalData to be worth approximately \$3 billion in 2010 and CF101 is one of only a few oral drugs developed for glaucoma. The market currently consists primarily of generic eye drop drugs. Oral administration is expected to improve patient compliance.

Q4 2015 Completion of patient enrollment for Phase II liver cancer trial

By the end of 2015, Can-Fite anticipates completing enrollment of approximately 78 patients in its Phase II trial for its drug candidate CF102 in the treatment of hepatocellular carcinoma

(HCC), the most common form of liver cancer. In December 2014, Can-Fite dosed its first patient in the randomized, double-blind, placebo controlled trial to be conducted in the U.S., Europe and Israel. CF102 has been granted Orphan Drug Status by the U.S. Food and Drug Administration and it is also approved for Compassionate Use for Liver Cancer by Israel's Ministry of Health. According to Global Industry Analysts the global market for liver cancer is projected to exceed \$2 billion by 2015.

Q4 2015 Completion of a working plan for Phase I Sexual Dysfunction trial

During 2015 Can-Fite, plans to implement a pre-clinical development program of its next generation drug CF602 for the indication of sexual dysfunction and develop a working plan to file an IND with the U.S. FDA for a Phase I study. In December 2014, Can-Fite received positive pre-clinical data from experimental animal models demonstrating that CF602 improved sexual dysfunction in a dose dependent manner. GlobalData estimates the value of the erectile dysfunction therapeutic market is approximately \$2.7 billion with few drugs on the market which includes Viagra, Cialis and Levitra.

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 and inflammatory diseases. The Company's CF101 is in Phase II/III trials for the treatment of psoriasis and the Company is preparing for a Phase III CF101 trial for rheumatoid arthritis. Can-Fite's liver cancer drug CF102 is commencing Phase II trials and has been granted Orphan Drug 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. 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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