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New Study Demonstrates CF602 Mechanism of Action to Improve Sexual Dysfunction

IND submission to FDA is planned for Q3 2016

PETACH TIKVA, Israel, Oct. 22, 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 reported new findings for its CF602 drug candidate showing a defined mechanism of action in erectile dysfunction similar to sildenafil (Viagra®) in a rat model of Diabetes Mellitus. Based on these latest findings, Can-Fite plans to file an Investigational New Drug application with the U.S. Food and Drug Administration (FDA) for CF602 in the third quarter of 2016.

New mechanism of action studies revealed that CF602 restores the impaired vascular endothelial growth factor system in the penis of Diabetes Mellitus rats, thereby inducing an increase in nitric oxide resulting in significant improvement of penile erection compared to placebo. This mechanism of action is similar to that of sildenafil, with CF602 demonstrating effects on erection superior to that demonstrated by sildenafil in animal studies. Sildenafil, sold by Pfizer as Viagra®, generated global sales of \$1.685 billion in 2014.

Among the most important factors to affect erectile function is nitric oxide which is released by endothelial cells that line the corpus cavernosum and control smooth muscle relaxation and vascular inflow. It has been well established that release of nitric oxide is diminished in diabetes. According to the American Diabetes Association, approximately 30 million Americans have Diabetes Mellitus in the U.S. and 35-75% of men with Diabetes Mellitus suffer from erectile dysfunction.

"We are very encouraged by these latest findings for our CF602 drug candidate which further validate the studies that are forming the basis of our planned IND submission to the FDA. We have a robust intellectual property portfolio which includes an issued composition of matter patent and other pending patent applications protecting the use of CF602 for sexual dysfunction and are positioning CF602 as a potential alternative to sildenafil (Viagra®)," stated Can-Fite CEO Dr. Pnina Fishman.

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.

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