Can-Fite Subsidiary, OphthaliX, Announces Completion of Patient Enrollment in Phase II Glaucoma Study for CF101

CF101 is one of only a few oral drugs being developed for the glaucoma market estimated to be \$3 billion in 2023

PETACH TIKVA, Israel, Dec. 7, 2015 /PRNewswire/ -- <u>Can-Fite BioPharma Ltd</u>. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, announced today that its subsidiary, OphthaliX (OTCQB:OPLI), has completed patient enrollment for its Phase II trial of CF101 in the treatment of glaucoma.

GlobalData estimates that the treatment market for glaucoma in the seven major markets was \$2.4 billion in 2013 and will grow to approximately \$3 billion by 2023. Most glaucoma drugs on the market today are generic eye drops. The key advantages of CF101 are its oral administration and excellent safety profile.

The Phase II trial is being conducted in Europe and Israel and full enrollment of 88 patients has been achieved. Top line results are expected in mid-2016. The study is being conducted with two cohorts. In the first cohort patients were treated with 1 mg CF101 and placebo. Blinded results from this cohort showed that the drug had a favorable safety profile and was well tolerated. In the second cohort, dosage was increased, with patients receiving 2 mg of CF101 and matching placebo, given orally every 12 hours for 16 weeks. The drug's mechanism of action has been validated in an article by a leading researcher from University College London in the UK, Dr. Cordiero, who showed that the A3 adenosine receptor (A3AR) agonist has a neuroprotective effect in the eye via inhibition of retinal ganglion cell apoptosis resulting in a significant decrease in intraocular pressure (IOP).

"Glaucoma is a substantial global market in which CF101 is one of only a few oral drugs in development. Oral drugs like CF101 have the potential to increase patient compliance and be more convenient for the patient," stated Can-Fite CEO Dr. Pnina Fishman. "In prior human clinical studies, we've seen that CF101 reduced IOP, the most important and only modifiable risk factor for glaucoma."

CF101 has an issued patent in the U.S. for the reduction of IOP, which expires in 2030. Several similar applications are pending in major global markets. OphthaliX has licensed the exclusive rights for the use and development of CF101 in the field of ophthalmic diseases from Can-Fite.

CF101, an A3 adenosine receptor (A3AR) agonist, is a novel, first in class small molecule orally bioavailable drug which binds with high affinity and selectivity to the A3AR, which is known to be over-expressed in inflammatory cells. The drug acts as a neuro-protective agent and prevents apoptosis of retinal ganglion 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 multibillion 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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