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Can-Fite Announces 2016 Clinical Milestones for its Pipeline of Drugs in Six Indications

- Phase III trials in rheumatoid arthritis and psoriasis expected to commence in 2016

- Planning Phase II trial for new indication in NASH

- Data expected in Phase II glaucoma trial

- Completion of patient enrollment anticipated in Phase II liver cancer trial

PETACH TIKVA, Israel, Jan. 11, 2016 /PRNewswire/ --Can-Fite BioPharma Ltd. (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, today announced its anticipated clinical milestones for calendar year 2016.

Q1 2016 Rheumatoid Arthritis Phase III EMA Submission for CF101

In the first quarter of 2016, Can-Fite plans to file its Phase III protocol with the European Medicines Agency (EMA) for CF101 in the treatment of rheumatoid arthritis. Initiation of patient enrollment is anticipated in the second or third quarter of 2016. Can-Fite recently filed a trial protocol with the institutional review board (IRB) of Barzilai Medical Center in Israel, one of the planned clinical sites for the international trial to be conducted in Israel, Europe, Canada and the U.S. The Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study will investigate the efficacy and safety of CF101 administered orally twice daily for 16 weeks to patients with active rheumatoid arthritis treated with conventional drugs. The study will have three arms, a 1 mg CF101 dose, a 2 mg CF101 dose, and placebo, given orally twice daily in the form of tablets. Approximately 456 patients are expected to be enrolled in the study. According to Visiongain, the global rheumatoid arthritis market is forecasted to reach $38.5 billion by 2017.

H1 2016 Psoriasis Phase III EMA Submission for CF101

Can-Fite is now completing the design of its Phase III study protocol for CF101 in the treatment of psoriasis which the Company plans to file with the EMA in the first half of 2016 and anticipates initiating patient enrolment in the fourth quarter of 2016. The Company previously reported positive data from further analysis of its completed Phase II/III study that suggests CF101 as a potential systemic therapy for patients with moderate-severe psoriasis, this despite the study not meeting its primary endpoint. The psoriasis drug market is forecast to grow to $8.9 billion by 2018, according to estimates of Visiongain.

H1 2016 Liver Cancer Phase II Completion of Patient Enrollment for CF102

Can-Fite anticipates completing enrollment of approximately 78 patients during the first half of 2016, in its Phase II trial for CF102 in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. The randomized, double-blind, placebo controlled trial is being conducted in the U.S., Europe and Israel. CF102 received Fast Track Designation from the U.S. FDA as a second line treatment for HCC in patients who have previously received Nexavar (sorafenib). The drug has Orphan Drug Status in the U.S. and in Europe for the treatment of HCC. CF102 is approved for Compassionate Use for liver cancer by Israel's Ministry of Health. According to Global Industry Analysts the global market for liver cancer was projected to exceed $2 billion by 2015.

Q2 2016 NASH Phase II Study Protocol Submission to IRBs for CF102

Can-Fite plans to file a Phase II study protocol with IRBs for its first human clinical study of CF102 in the treatment of non-alcoholic steatohepatitis (NASH), a new indication identified by the Company for its liver cancer drug. In November 2015, Can-Fite announced compelling pre-clinical data on CF102 in the treatment of NASH, a disease for which no FDA approved therapies currently exist. By 2025, Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach $35-40 billion in size.

Q2 2016 Glaucoma Phase II Data Report for CF101

Can-Fite expects data from its Phase II study of CF101 in the treatment of glaucoma to be reported during the second quarter. Enrollment of 88 patients was recently completed in the study which is being conducted in two European countries and Israel by Can-Fite's subsidiary OphthaliX Inc. The treatment market for glaucoma in the seven major markets is estimated to reach approximately $3 billion by 2023 according to GlobalData and CF101 is one of only a few oral drugs being developed for glaucoma. The market currently consists primarily of generic eye drop drugs. Oral administration is expected to improve patient compliance.

Q4 2016 Sexual Dysfunction IND/Phase I Study Filing with U.S. FDA for CF602

Can-Fite has an active pre-clinical development program for its next generation drug CF602 in the treatment of sexual dysfunction and is currently developing a working plan to file an investigational new drug (IND) application with the U.S. FDA for a Phase I study during the fourth quarter of 2016. 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 to be approximately $2.6 billion by 2018 with few drugs on the market which includes Viagra, Cialis and Levitra.

"We are very encouraged by the clinical and preclinical data from each of our drugs to date which indicate their efficacy across six major indications. We are moving towards initiating pivotal Phase III trials in two autoimmune diseases. As we look forward to announcing Phase II results for glaucoma and completing Phase II enrollment for liver cancer, we are preparing to enter human clinical studies in two new indications, NASH and sexual dysfunction. We expect 2016 will be a very active year," 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 Phase III 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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