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Can-Fite Files Clinical Trial Application in Canada for Piclidenoson Ahead of Upcoming Acrobat Rheumatoid Arthritis Phase III Study

PETACH TIKVA, Israel, May 16, 2017 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today it has filed a Clinical Trial Application (CTA) with Health Canada for Piclidenoson. Can-Fite has a Canadian distribution partner, [Cipher Pharmaceuticals](#) Inc. (Cipher) (TSX: CPH).

Can-Fite intends to commence its Phase III Acrobat trial of Piclidenoson in the treatment of rheumatoid arthritis in the second quarter of 2017.

"We look forward to a positive response from Health Canada to our CTA so that we may begin enrolling patients in Canada for our upcoming Phase III study. Having recently received Institutional Review Board (IRB) approvals in Israel for our rheumatoid arthritis trial, we are ready to expand into clinical sites in Canada and Europe," said Can-Fite CEO Dr. Pnina Fishman.

"New therapies are needed for people who face the tremendously debilitating symptoms of rheumatoid arthritis," said Robert Tessarolo, President and CEO of Cipher Pharmaceuticals. "We are looking forward to a positive outcome from the Piclidenoson Phase III clinical program to help manage this chronic disease."

About Piclidenoson (CF101)

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical studies. Piclidenoson is currently under development for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis and psoriasis, both set to commence Phase III.

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 autoimmune-inflammatory indications, oncology and liver diseases as well as sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is headed into Phase III trials for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug Namodenoson is in a Phase II trial for patients with liver cancer and is slated to enter another Phase II for the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH). Namodenoson 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. Namodenoson has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. CF602, the Company's third drug candidate, has shown efficacy in the treatment of erectile dysfunction in preclinical studies. These drugs have an excellent safety profile with experience in over 1,000 patients in clinical studies to date. For more information please visit: www.can-fite.com.

About Cipher Pharmaceuticals Inc.

Cipher (TSX:CPH) is a specialty pharmaceutical company with a robust and diversified portfolio of commercial and early to late-stage products. Cipher acquires products that fulfill unmet medical needs, manages the required clinical development and regulatory approval process, and markets those products either directly in Canada or indirectly through partners in Canada, the U.S., and South America. For more information, visit www.cipherpharma.com.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, market risks and uncertainties and Can-Fite's ability to satisfy all the conditions to the closing of the proposed offering, 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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