

# Can-Fite: Topical Administration of CF602 Fully Recovers Erectile Dysfunction in Diabetic Model

- *Issued Patents in major markets including the U.S., Australia, China, and Japan*

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced new data from a preclinical study of its drug candidate CF602 in the treatment of erectile dysfunction (ED) in diabetes experimental model.

The study evaluated the efficacy of topically applied CF602 in a 4-cohort study with diabetic Sprague-Dawley (SD) rats receiving placebo; 100nM CF602; 500nM CF602. Naïve rats served as a comparative negative control. ED was assessed by tracing Intracavernous Pressure (ICP) under cavernous nerve stimulation.

Treatment with CF602 at a dose of 500 nM resulted in statistically significant improvement of erectile dysfunction compared to vehicle treated controls when measured in a two-way ANOVA followed by Bonferroni multiple comparisons post-hoc analysis ( $p < 0.001$ ). The improvement was even better than recorded for the naïve animals group. Efficacy was dose-dependent.

“Based on these very compelling data, we believe CF602 is an ideal candidate for development due to the topical drug’s proven efficacy in a diabetes pre-clinical model, and the massive size of the ED market. ED is a common complication of diabetes and is difficult to treat with systemic drugs due to the high risk profile of these patients. As a topical formulation, CF602 may offer distinct safety and efficacy advantages over oral ED drugs on the market today,” stated Can-Fite CEO Dr. Pnina Fishman.

Diabetic patients reportedly experience more severe ED and are diagnosed 10–15 years earlier than the general population. According to the American Diabetes Association, approximately 30 million Americans have diabetes mellitus in the U.S. It is estimated that 35-75% of men with diabetes mellitus suffer from ED.

Grand View Research estimates the value of the ED therapeutic market will reach approximately \$3.2 billion by 2022.

## About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: 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, liver, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver

drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint in a Phase II trial for the treatment of 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 HCC 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. These drugs have an excellent safety profile with experience in over 1,500 patients in clinical studies to date. For more information please visit: [www.can-fite.com](http://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, market risks and uncertainties, 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. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; the impact of the COVID-19 pandemic; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed 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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