

January 24, 2019

# Can-Fite BioPharma CEO Letter to Shareholders

**Near term milestones include:**

- **Advanced Liver Cancer Phase II data release**
- **NAFLD/NASH Phase II data release**

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 cancer, liver and inflammatory diseases, today announced that Pnina Fishman, Chief Executive Officer of Can-Fite Biopharma, has issued a Letter to Shareholders, the full text of which follows below.

**Dear Can-Fite Shareholders,**

It has been a very busy and productive year at Can Fite BioPharma, filled with clinical and business development activities. Our main interest is patients, for whom we are working towards drugs that combine a unique profile of safety and efficacy.

Can-Fite BioPharma achieved a significant number of milestones in 2018:

## **Clinical Activities**

### **Piclidenoson for the Treatment of Rheumatoid Arthritis and Psoriasis–**

During 2018, we continued to enroll patients for the ACRobat™ Phase III trial of our lead drug candidate, Piclidenoson, in the treatment of rheumatoid arthritis and in August 2018, we initiated patient enrolment for a the Comfort™ Phase III psoriasis trial.

Can Fite's main goal for these two clinical indications, addressing together an estimated \$45B market by 2020, is to develop Piclidenoson as a safe single first line drug for chronic treatment.

### **Namodenoson for the Treatment of Liver Diseases–**

**Advanced Liver Cancer:** Can Fite is unique in developing a drug for advanced liver cancer Child Pugh B stage patients who failed Nexavar (sorafenib) as a first-line treatment. During 2018, we reported that accumulated safety data at the time continues to indicate a favorable safety profile. We further announced that due to patient survival, top-line results of the Namodenoson Phase II advanced liver cancer study are expected to be released in Q1 2019.

**NAFLD/NASH:** We continue to enroll patients for a Phase II trial of Namodenoson for the treatment of 60 patients with nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). For this indication, current treatment options are limited and the

market for NASH therapies is estimated to reach \$35-40 billion by 2025.

## **New Partnerships**

### Gebro Pharma

In January 2018, Can-Fite signed a distribution agreement with Gebro Holding GmbH to distribute Piclidenoson for the treatment of rheumatoid arthritis and psoriasis, in three European countries (Spain, Switzerland and Austria). Under the terms of the distribution agreement, Gebro paid a total upfront payment of \$2.2 million to Can-Fite upon signing of the agreement and an additional milestone payment of 300,000 Euros upon the initiation of the Comfort Phase III psoriasis clinical study. The agreement provides that additional payments of up to approximately \$7 million are due upon the achievement of certain regulatory, launch and sales milestones plus double-digit percentage royalty payments on net sales.

### CMS Medical:

In August 2018, Can-Fite signed a License, Collaboration and Distribution agreement with CMS Medical Venture Investment Limited for the development and commercialization of Piclidenoson for the treatment of rheumatoid arthritis and psoriasis and Namodenoson for the treatment of advanced liver cancer and NAFLD/NASH in China (including Hong Kong, Macao and Taiwan). Under the terms of the agreement, CMS Medical made an upfront payment of \$2 million to Can-Fite and is required to pay to Can-Fite milestone payments of up to \$14 million upon the achievement of certain regulatory milestones and payments of up to \$58.5 million upon the achievement of certain sales milestones. In addition, the agreement provides for double-digit royalty payments on net sales.

**We look forward to the rest of 2019 which promises to be an event driven year. We have a number of important milestones in the coming months and look forward to providing you with ongoing updates on our clinical and commercial progress.**

Sincerely,

Pnina Fishman, Ph.D.

Chief Executive Officer

### **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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and 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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. 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](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: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; 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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