

# Can-Fite 12 Months' Activities & Milestones for 2018

*Expected milestones in the next 12 months include:*

- *Two Phase III studies in rheumatoid arthritis and psoriasis*
- *Data release from the Phase II liver cancer trial*
- *Complete enrollment for the NASH study*

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 its near-term milestones for 2018, including events related to the rheumatoid arthritis/psoriasis drug Piclidenoson and the liver disease drug Namodenoson.

The Company believes that it is close to reaching certain significant clinical milestones in its efforts to bring the two lead drug candidates, Piclidenoson and Namodenoson, to market. Both drug candidates are administered to patients orally in the form of a tablet and have demonstrated an excellent safety profile in prior clinical trials. The below near-term key events provide an outlook of Can-Fite's objectives and potential for increased growth.

## **Piclidenoson**

- **A pivotal Phase III study**, ACRobat®, for the treatment of patients with rheumatoid arthritis is currently enrolling patients to evaluate the drug as a first line treatment and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis.
- **A pivotal Phase III study**, Comfort®, for the treatment of patients with moderate-to-severe plaque psoriasis in comparison to placebo and as compared to apremilast (Otezla®) is expected to commence during 2018.

Can-Fite expects that these pivotal Phase III studies will serve as the first of two pivotal studies required for European Medicines Agency (EMA) drug approval.

## **Namodenoson**

- **Top-line results** from the ongoing Phase II study with Namodenoson for patients with advanced liver cancer is expected in the second half of 2018. Enrollment of all 78 subjects in Israel, Europe and the U.S. has been completed and the Company continues to follow up on patients' overall survival.
- **Phase II study in patients with NAFLD/NASH** has commenced in Israel, and is expected to enroll approximately 60 patients. The Company aims to complete enrollment for this study in the next twelve months.

## **Biomarker**

- The Company has already developed a high throughput screening assay which is conducted in a central lab for the evaluation of the A3AR Biomarker in a small blood sample withdrawn from the patients in each of the trials. The purpose of analyzing the biomarker prior to treatment is to help identify an individual patient's responsiveness to the Company's drugs, providing more personalized medicine. In case a direct correlation between biomarker level prior to treatment and patients' response to the drug is demonstrated, the Company expects this to have additional commercial applications. The U.S. Patent and Trademark Office previously issued a patent for the utilization of A3AR as a biomarker to predict patient response to Piclidenoson in autoimmune inflammatory indications.

"We are very excited at the opportunity of potentially receiving further validation of our drug candidates, which represents significant steps forward in our commitment to delivering treatments to patients. We hope to see this come to fruition upon conclusion of our various trials," stated Can-Fite CEO Dr. Pnina Fishman.

Can-Fite's Piclidenoson and Namodenoson are focused on multibillion-dollar market opportunities. The rheumatoid arthritis and psoriasis therapeutic market is dominated by biological drugs that are primarily administered via intravenous injection (IV) and have potential side effects. Rheumatoid arthritis and psoriasis are huge unmet-need markets, where rheumatoid arthritis is estimated to reach \$35B in 2020 and psoriasis is forecast to reach \$9B in 2018.

### 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 multibillion-dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis during 2018. 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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Source: Can-Fite BioPharma