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Can-Fite Implements Interim Analysis for its Phase III Psoriasis Trial with Data Expected Q4 2020

PETACH TIKVA, Israel--(BUSINESS WIRE)--

[Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, announced today it is implementing an interim analysis of the Phase III Comfort™ trial designed to evaluate the Company's drug candidate, Piclidenoson, in the treatment of moderate-to-severe plaque psoriasis. Following the independent data monitoring committee's evaluation of the data, Can-Fite expects to announce interim results in the fourth quarter of 2020.

The Comfort™ Phase III psoriasis study is designed to establish Piclidenoson's superiority compared to placebo and non-inferiority compared to Apremilast (Otezla®) in patients with moderate to severe plaque psoriasis. The randomized, double blind study is being conducted in Europe, Israel, and Canada. The study's primary endpoint is the proportion of subjects who achieve a PASI score response of $\geq 75\%$ (PASI 75) vs. placebo at week 16. The secondary endpoints include non-inferiority to Otezla® on weeks 16 and 32. A Drug Safety Update Report filed in February 2020 with regulatory agencies reported that Piclidenoson, which has been dosed in over 1,400 patients, is well tolerated and has no emerging safety concerns.

"By implementing this interim analysis, we gain earlier access to data on Piclidenoson's efficacy in the treatment of psoriasis, as well as more safety data on Piclidenoson, which is also currently being evaluated as a treatment for rheumatoid arthritis, and being considered as a potential treatment for COVID-19. By increasing the amount of data available, we believe we will accelerate our development timelines across each indication, and also optimize the use of our corporate resources," stated Can-Fite CEO Dr. Pnina Fishman.

Piclidenoson has been out-licensed for the indication of psoriasis in Canada, South Korea, Spain, Austria, Switzerland, Hong Kong, Macau, Taiwan, and China. According to iHealthcareAnalyst, the psoriasis therapeutic market is estimated to reach \$11.3 billion by 2025.

Important Message Regarding COVID-19

Public health epidemics or outbreaks could adversely impact our business. In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China. While initially the outbreak was largely concentrated in China, it has now spread to several other countries, including in Israel, and infections have been reported globally. The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus.

or treat its impact. In particular, the continued spread of the coronavirus globally, could adversely impact the Company's operations and workforce, including the Company's research and clinical trials and ability to raise capital, which in turn could have an adverse impact on the Company's business, financial condition and results of operation.

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, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is 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.

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 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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