

# Can-Fite is Developing a Topical Piclidenoson Psoriasis Treatment that Shows Efficacy in a Preclinical Model: Potential Complementary Product to its Phase III Oral Psoriasis Drug

- *Topical psoriasis treatments account for 42% of the \$11.37 billion psoriasis drug market*
- *Topline results from Phase III oral Piclidenoson study expected Q2 2022*
- *Piclidenoson has been out-licensed for the systemic indication of psoriasis in certain major markets*

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 it is developing a topical psoriasis treatment with Piclidenoson, its Phase III psoriasis oral drug candidate. The Company's scientists reported that in a preclinical model, imiquimod-induced skin psoriasis, daily treatment with topical Piclidenoson significantly inhibited the disease as measured by the psoriasis area severity index (PASI) calculated based on observation of erythema, thickness, scaling, and a score of skin lesions.

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule drug with a favorable therapeutic index demonstrated in Phase II clinical studies.

The Company expects to announce topline results during Q2 2022 from its Phase III randomized, double blind, active and placebo-controlled study conducted in Europe, Israel, and Canada. The study's primary endpoint is the proportion of patients who achieve a PASI score response of  $\geq 75\%$  (PASI 75) vs. placebo at week 16 and secondary endpoints include non-inferiority vs. Otezla®.

"The current preclinical data are important and serve as a basis for further development of a topical Piclidenoson treatment for psoriasis skin lesions, as it may serve as a good complementary product to our oral Piclidenoson drug. We are encouraged by the positive interim analysis reported last year from our Phase III oral Piclidenoson study based on data from 200 patients, and we hope that the data will be reproducible, offering patients safe and long term relief from the symptoms of psoriasis," stated Can-Fite CEO Dr. Pnina Fishman.

According to [Persistence Market Research](#), topical psoriasis treatments account for 41.7% of the psoriasis drug market which was valued at \$11.37 billion in 2021 and is projected to grow at a CAGR of 6.5% to \$21.48 billion by 2031.

Piclidenoson has been out-licensed for the indication of psoriasis in major markets including Canada, Europe, and Asia with deal terms including potential upcoming milestone payments

and double-digit royalties upon regulatory approval.

### **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, and inflammatory disease. The Company's lead drug candidate, Piclidenoson has completed enrollment in a Phase III trial for psoriasis. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH), and enrollment is expected to commence in a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer. 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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