November 23, 2021

Can-Fite's Piclidenoson Commences Clinical Study for the Treatment of Canine Osteoarthritis

- ***Study conducted and costs covered by Vetbiolix, Can-Fite's development and commercialization partner for the veterinary market***
- ***Canine osteoarthritis, a market projected to reach $3 billion by 2024, has a shorter path to regulatory approval and commercialization than human indications***

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 that its veterinary development and commercialization partner Vetbiolix, a France-based veterinary biotech company, has commenced a safety and efficacy study of Piclidenoson for the treatment of osteoarthritis in dogs. Safety results are expected Q1 2022 and efficacy data is expected Q4 2022. Piclidenoson has been widely tested in human clinical trials and has a favorable safety profile across more than 1,500 human patients.

As an oral drug with an excellent safety profile in human clinical trials, Piclidenoson may offer a much needed, safe, and effective treatment for canine osteoarthritis. The most commonly used current treatments for this indication include oral non-steroidal anti-inflammatory drugs (NSAIDs) for pain control which carry significant harmful side effects, and an injectable disease modifying osteoarthritis drug (DMOAD) that targets the progression of disease.

In the U.S. approximately 23 million dogs are diagnosed with some form of arthritis, and about 20%-25% of dogs have osteoarthritis. The chronic joint disease is characterized by loss of joint cartilage, thickening of the joint capsule, and new bone formation around the joint that leads to limb dysfunction and pain. The canine osteoarthritis market is projected to reach $3 billion by 2024.

"Based on Piclidenoson's safety profile in humans and small animals, we expect similar excellent results in dogs. We are hopeful that Piclidenoson may also show efficacy in osteoarthritis and offer relief to millions of dogs and their families. Working with Vetbiolix for this veterinary indication, our aim is to leverage our clinical pipeline to benefit animals while accelerating our path to commercialization through a capital efficient strategy," stated Can-Fite CEO Dr. Pnina Fishman.

Vetbiolix is responsible for all costs and development of Piclidenoson in the veterinary osteoarthritis market for dogs and cats, for which Vetbiolix has the exclusive rights to Piclidenoson for two years under an option agreement. Should the clinical studies yield positive data and Vetbiolix exercises its option to license from Can-Fite, then Vetbiolix will be obligated to pay Can-Fite upfront and milestone payments, in addition to royalties on sales upon regulatory approval for veterinary use.

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 a Phase IIb 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 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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Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

Source: Can-Fite BioPharma Ltd.