June 28, 2021

Can-Fite Enters Projected $3 Billion Veterinary Osteoarthritis Market: Signs Agreement with Vetbiolix for Development of Piclidenoson for Pets

- ***All pre-clinical, clinical, and regulatory development work to be conducted and financially covered by Vetbiolix***
- ***Veterinary market has potential for a shorter path to regulatory approval and product revenues***

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 has signed a development and commercialization agreement with Vetbiolix, a France-based veterinary biotech company, for the development of Piclidenoson for the treatment of osteoarthritis in companion animals including dogs and cats.

Vetbiolix will have the exclusive right to Piclidenoson in the veterinary osteoarthritis market for two years, during which time Vetbiolix will conduct proof-of-concept studies and cover all associated costs. If the studies yield positive data and Vetbiolix exercises its option to obtain the 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.

The canine osteoarthritis market is projected to reach $3 billion by 2024. According to Grand View Research, the broader global companion animal health market is estimated at a value of $20 billion in 2021 and is expected to grow to $27 billion by 2028.

Current treatments for canine osteoarthritis include oral non-steroidal anti-inflammatory drugs (NSAIDs) which only treat symptoms and carry significant harmful side effects, and an injectable disease modifying osteoarthritis drug (DMOAD) that targets the progression of the disease. Piclidenoson, an oral drug that has a favorable safety profile in humans and in animal studies, offers a potentially safe and effective oral treatment for canine osteoarthritis.

“The veterinary market is a significant opportunity where our drugs may have an impact. Both the size of the market and the shorter timelines to regulatory approval have the potential to result in milestone and royalty revenues for Can-Fite. We believe Piclidenoson’s safety and efficacy data in over 1,000 humans, as well as preclinical data from small animals, indicate it may offer relief to the growing number of companion animals with osteoarthritis,” stated Can-Fite VP of Business Development, Dr. Sari Fishman.

Matthieu Roquette, President at Vetbiolix commented, “The quality of preclinical and clinical data generated by Can-Fite on Piclidenoson and its pharmacological profile make this highly selective A3 Adenosine Receptor Agonist a drug candidate likely to meet the unmet

veterinary medical need to date in the management of osteoarthritis pathology in dogs and cats. Moreover, the mechanism of action of Piclidenoson makes this product a strong candidate for a large spectrum of inflammatory disease indications affecting Pets. We are aiming to enter in veterinary regulatory development by the end of 2022 based on clinical proof of concept data we will generate within the next 12 months."

In 2019, the U.S. Patent and Trademark Office issued to the Can-Fite patent #10,265,337 titled "Use of A3 Adenosine Receptor Agonist in Osteoarthritis Treatment" for Piclidenoson in the treatment of osteoarthritis in mammals.

About Vetbiolix

Vetbiolix develops innovative products for treatment and prevention of diseases affecting pets. As pharmaceutical and biotech companies research novel molecules and compounds for human medicine, tests in different species often reveal exciting possibilities for pets. Vetbiolix has developed a unique approach focused on turning this potential into innovative prescription medicines and care products for pets. To date, veterinarians have still few therapeutics and real preventive care products at their disposal that have been specifically developed and approved for pets. Along with a virtual VetBiotech organization, Vetbiolix exclusively focuses on clinical developments of prescription medicines, diagnostics, nutraceuticals and care products for pets, thanks to its qualified external R&D partners in Europe & the US. Vetbiolix is supported by the Eurasanté Bio-Incubator, the northern France health cluster ranked among the top 20 best European incubators fostering pharm/biotech start-up development (Labiotech.eu 2019).

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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Source: Can-Fite BioPharma Ltd.