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Can-Fite's Partner Vetbiolix is Heading into a European Multicentric Clinical Trial with Piclidenoson for the Treatment of Pets' Osteoarthritis

The canine osteoarthritis market is projected to reach $3 billion by 2028

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 progress achieved in the development of Piclidenoson for` the treatment of osteoarthritis in dogs by the Company's veterinary commercialization partner Vetbiolix, which is covering all costs associated with veterinary clinical development. The canine osteoarthritis market is projected to reach $3 billion by 2028.

Vetbiolix completed dose-ranging pharmacokinetic (PK) studies in dogs and determined the optimal efficacy and safety dosage for its upcoming European multicentric clinical study. Piclidenoson was well tolerated, with the PK data proportional to dose. Pre-clinical studies were also conducted showing Piclidenoson has a very favorable safety profile.

Based on these data, Vetbiolix has designed a European Multicentric Clinical study protocol for dogs with osteoarthritis which has been approved by an ethical committee.

There is clear need in the market for a safe and effective canine osteoarthritis drug. 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.

"As Piclidenoson advances into a European Multicentric Clinical study for canine osteoarthritis in 2023, we are hopeful that our lead drug candidate, which has produced very good safety and efficacy results in human autoimmune diseases, will do the same for dogs," stated Can-Fite CEO Dr. Fishman. "This veterinary indication offers Can-Fite the opportunity to get Piclidenoson onto the market faster to benefit canines, while also potentially contributing near-term revenues. We are very pleased to work productively with the team at Vetbiolix."

In June 2021, Can-Fite entered an agreement with Vetbiolix, a France-based veterinary biotech company, for the treatment of osteoarthritis in companion animals including dogs and cats. Vetbiolix has the exclusive right to Piclidenoson in the veterinary osteoarthritis market for two years, during which time Vetbiolix is conducting studies and covering all associated costs. If the efficacy study yields 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.

About Piclidenoson

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with an excellent safety and efficacy profile demonstrated in a Phase III clinical study in psoriasis. The drug's mechanism of action entails inhibition of the inflammatory cytokines interleukin 17 and 23 (IL-17 and IL-23) and the induction of apoptosis of patients' skin cell keratinocytes involved with the disease pathogenicity.

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 recently reported topline results 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.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, 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; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the "Risk Factors" section of Can-Fite's Annual Report on Form 20-F filed with the SEC on March 24, 2022 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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