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Significant Positive Results from Osteoarthritis Clinical Study in Dogs Treated with Piclidenoson

Data Reported by Can-Fite Veterinary Partner Vetbiolix who already exercised its option for a full license deal worth $325M

Ramat Gan, Israel, Oct. 18, 2024 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced that its veterinary partner Vetbiolix reported positive final results from the osteoarthritis multicenter clinical study in dogs treated with Piclidenoson. Vetbiolix, Can-Fite's veterinary commercialization partner, which is covering all costs associated with veterinary clinical development, successfully concluded the full study.

Vetbiolix already exercised its option to enter into a full in-license agreement with Can-Fite and is obligated to pay Can-Fite an upfront payment, milestone payments and royalties on sales upon regulatory approval, summing up to projected income of $325M to Can-Fite over the next 10 years.

The study looked at the effect of 90 days treatment with Piclidenoson at 100 µg/kg and 500 µg/kg twice daily orally in dog patients with osteoarthritis. Including all evaluable patients, the primary objective was the Liverpool OsteoArthritis in Dogs (LOAD) questionnaire for the assessment of symptoms severity evaluated on dog's mobility. The secondary objectives included Visual Analog Scale (VAS) for pain assessment by pet parents and Numerical Rating Score (NRS) for (i) lameness and (ii) pain assessment by the veterinarian. The study reached the primary and secondary endpoints with a dose and time dependent inhibitory effect of Piclidenoson on LOAD and VAS, together with a favorable trend on NRS scores, demonstrating significant improvement in clinical status and decrease in pain utilizing the 500 µg/kg dose.

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

There is a 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.

"The final data from the osteoarthritis study are very encouraging and this veterinary indication offers Can-Fite the opportunity to get Piclidenoson onto the market faster to benefit canine, and potentially contribute to near-term revenues. We are very pleased to work productively with the team at Vetbiolix." stated Can-Fite VP of business Development Dr. Sari Fishman.

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: CANF) 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 NASH a Phase III trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic 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 1,600 patients in clinical studies to date. For more information please visit: www.canfite.com.

About VETBIOLIX SAS

VETBIOLIX develops innovative products for the treatment and prevention of diseases affecting pets. VETBIOLIX has built a unique pipeline of *First-in-class* oral small molecules in-licensed (*exclusive and worldwide license*) from Human Biotech worldwide which will answer to veterinary unmet medical needs in periodontitis (*VBX-1000; Cathepsin-K inhibitor*), osteoarthritis (*VBX-2000; Adenosin-A3 agonist*) and gut motility disorders (VBX-3000; 5-HT4 agonist). VETBIOLIX focuses exclusively on clinical developments of its drug candidates: the company invests on (i) clinical proof of concept studies, (ii) CMC-Pharmaceutical developments, (iii) regulatory Pilot clinical studies and (iv) regulatory Pivotal clinical studies. Revenue generation of the company will be based on out-licensing and/or co-developments deals with the Veterinary Pharmaceutical Industry.

For more information please visit: https://www.vetbiolix.com

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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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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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