September 18, 2017

# Can-Fite Files Patent Application to Treat Cytokine Release Syndrome, a Potentially Life-Threatening Complication of CAR-T Cell Therapy

- ***The CAR-T market, a growing segment within cancer treatment, is estimated to reach approximately $4.5 Billion in 2022 according to Evaluate Pharma***
- ***Cytokine release syndrome (CRS) is a potentially fatal side effect of CAR-T and other immune-oncology therapies induced by massive release of inflammatory cytokines***
- ***Can Fite's drugs robustly inhibit the release of inflammatory mediators that induce CRS by binding to the A3 adenosine receptor***

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 cancer, liver and inflammatory diseases, today announced it has filed a patent application to protect the use of its drugs and other ligands which target the A3 adenosine receptor (A3AR) to treat cytokine release syndrome (CRS).

"CAR-T and other cancer immunotherapies are a very promising category of drugs and may shape the treatment of cancer in the future. When they work, they can save lives, however, a concern that needs to be addressed with this class of treatment is the relatively high incidence of CRS, a side effect which can kill patients. We believe our drugs, which bind to A3AR, have the potential to treat CRS, which could make CAR-T and other immuno-oncology drugs safer for patients," stated Dr. Pnina Fishman, Can-Fite's CEO. "A safe and effective treatment for CRS that does not inhibit the efficacy of CAR-T and other immuno-oncology therapies meets a growing unmet medical need in the treatment of cancer."

CAR-T cell therapies are designed to treat certain cancers by modifying an individual patient's own immune cells to specifically target their cancer cells. CRS, which is caused by an overactive immune response to the treatment, has been identified as a potentially severe and life-threatening side effect of CAR-T cell therapies.

While most people with CRS experience mild or moderate flu-like symptoms which are easily managed, some patients experience more severe symptoms that may lead to potentially life-threatening complications such as cardiac dysfunction, acute respiratory distress syndrome or multi-organ failure. One recently approved CAR-T therapy shows 79% of patients receiving the treatment got CRS and 49% got severe CRS, according to the drug's prescribing information.*

Can Fite's platform technology selectively targets A3AR, which plays a central role in mediating the mechanism of inflammation by reducing elevated levels of pro-inflammatory cytokines such as IL-6, IL-1β, NF-Kβ, TNF-α, and more. As such, the Company believes that

A3AR targeting may serve as an important treatment option for patients in reducing the risk of CRS without limiting the utility of the underlying cancer immunotherapy.

Current treatment for CRS includes aggressive immunosuppression through the use of high doses of corticosteroids to reverse the syndrome. However, while corticosteroids may control some of these toxicities, their potential to block T-cell activation and negate the clinical benefit of CART-T is a concern (Maude SL, et al, Cancer J, 2014). ACTERMA® (tocilizumab), in August 2017 became the first FDA approved treatment for severe CRS induced by CAR-T, however it can mediate the immunosuppressive effect which could limit the efficacy of the immunotherapy (Lee et al, Blood, 2014).

In addition to CAR-T, CRS is also associated with therapeutic monoclonal antibody (mAb) infusions, most notably anti-CD3 (OKT3), anti-CD52 (alemtuzumab), anti-CD20 (rituximab), and the CD28 super-agonist, TGN1412.

*The recently approved CAR-T cell immunotherapy, KYMRIAH® (tisagenlecleucel), reveals in its prescribing information notes that in its registration study, 79% (54/68) of patients receiving the drug developed CRS, with the median time to onset of 3 days (range: 1-22 days). The incidence of severe CRS, Grade 3 or Grade 4, was 49% (33/68).

About Can Fite's Drugs

Can-Fite's platform technology utilizes the Gi protein associated A3 adenosine receptor (A3AR) as a therapeutic target. A3AR is highly expressed in inflammatory and cancer cells where low expression is found in normal cells, suggesting that the receptor could be a unique target for pharmacological intervention. The Company's drugs have an excellent safety profile with experience in over 1,000 patients. Piclidenoson (CF101) is expected to enter Phase III trials in two auto-immune indications and Namodenoson (CF102) completed patient enrollment in a Phase II liver cancer trial and is slated to enter Phase II for the treatment of NAFLD/NASH.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is scheduled to enter a Phase III trial for rheumatoid arthritis in 2017 and a Phase III trial for psoriasis in early 2018. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug CF102 is in Phase II trials for patients with liver cancer and is slated to enter Phase II for the treatment of non-alcoholic steatohepatitis (NASH). CF102 has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. These drugs have an excellent safety profile with experience in over 1,000 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: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; 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.

View source version on businesswire.com:
http://www.businesswire.com/news/home/20170918005310/en/

Can-Fite BioPharma
Motti Farbstein, +972-3-9241114
info@canfite.com

Source: Can-Fite BioPharma Ltd.