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Press Release

Can-Fite: Pre-clinical Studies demonstrate that the Excipients used in the Placebo and CF101 Drug Enhanced the Anti-inflammatory Effect of Methotrexate (MTX)

Pre-clinical studies conducted by Can-Fite following Phase IIb data release showed that the excipients used in the Placebo and in the CF-101 Drug during the Phase IIb RA study, enhanced the anti-inflammatory effect of Methotrexate (MTX)

Last week, Can-Fite reported that the Phase IIb trial had revealed that the combination of the excipient and the drug MTX improves the efficacy of MTX in treating rheumatoid arthritis

Can-Fite has filed a patent application to protect the excipient activity and is considering further development of its use

Can-Fite reports that laboratory trials have proven that the excipients included in the placebo used in its trial in combination with the drug MTX improves the drug's performance in treating rheumatoid arthritis.

Can-Fite lately reported the results of a Phase IIb clinical trial that had evaluated the safety and efficacy of a combination of CF101 and MTX in treating rheumatoid arthritis patients. A high number of patients (50%) responded with a 20% improvement in the disease indices (ACR20), both in the control group and in groups that had been treated with CF101 in combination with MTX. This percentage of responders in the control group is an unprecedented phenomenon, and is higher than that which has thus far been described in the literature. As a result, Can-Fite conducted the trials with the drug excipient and, indeed, found that it had acted as an anti-inflammatory substance and significantly enhanced the MTX drug efficacy.

The company's scientists have conducted pre-clinical laboratory studies with models simulating rheumatoid arthritis. These studies proved that the excipient in the placebo has biological activity that, in combination with the MTX, produces an anti-inflammatory effect. The excipient is an oil mixture containing Polyoxyl 45 Castor Oil and Miglyol 812. The aforementioned laboratory studies conducted by Can-Fite revealed that the excipients enhanced the anti-inflammatory activity of the drug methotrexate (MTX). In pre-clinical laboratory trials, Can-Fite scientists found that the excipients led to up-regulation of the 2 adenosine receptors, A3 and A2A which are known to mediate the effect of MTX. This finding explains the high activity observed in a group treated with MTX and placebo (the control group).

These results explain the high percentage of control group patients whose condition had improved.

As reported earlier, Can-Fite has applied for a patent that protects the biological activity of the excipient, and is even considering its development of the solvent as a supplement to the current rheumatoid arthritis treatments.

It should be noted that Can-Fite reported a significant improvement in the percentage of patients who had responded with a 50% and 70% improvement as well as in the EULAR 'Good' Response Score. Another important finding was that the patient response improvement had increased throughout the treatment period, indicating that a long-term trial would make it possible to observe continued improvement. The results further reveal that, in all the indices, the 1mg dose of CF101 was the most efficacious, a result which is important for the future drug development program. It should also be noted that the treatment combining CF101 and methotrexate had a high safety profile.

Prof. Pnina Fishman stated that the discovery that the excipient has significant biological activity that modulate the expression of the adenosine receptors on the surface of the inflammatory cells led to enhancement of the methotrexate activity. These results, for which Can-Fite registered a patent, can serve as a basis for developing another product for the benefit of those suffering from this disease.

Can-Fite Biopharma Ltd is a public company traded on the Tel-Aviv Stock Exchange. The Company, which commenced business activity in 2000, was founded by researcher Prof. Pnina Fishman and patent attorney Dr. Ilan Cohn. The Company focuses on the development of small molecule-based drugs which target the A3 adenosine receptor and inhibit the development of cancer or inflammatory cells. The market for the company's drugs is estimated at billions of dollars.

Can-Fite develops targeted drugs that specifically attack affected cells without compromising normal body systems, and therefore have a favorable safety profile. The Company's drugs are based on a scientific concept, which was proven in trials, suggesting that the A3 adenosine receptor, the target of the drug is only expressed on the surface of affected cells. The Company has recently developed a procedure that uses pre-treatment blood tests to determine the receptor level, which may be indicative of treatment response.

The Company's lead drug, CF101 has completed a multinational study in the treatment of rheumatoid arthritis and plans to continue to develop the drug for this indication. CF101 is also in clinical development for two other indications: Dry Eye Syndrome, for which a Phase II study is ongoing and Psoriasis where a Phase II study has recently started. The Company is also developing another small molecule drug, CF102, for treatment of liver cancer and hepatitis. CF102 is in pre-clinical development and the development is on target for filing an IND towards the end of this year and the onset of Phase I study shortly thereafter. The company also has a number of other small molecule drugs in earlier stages of development.

For details: Amir Eisenberg, 0528-260285; Shai Eliash 0522-546635; Liron Singer 0525-476661; Inbal Levi 0524-022274; Miri Riley 0524-022275; Office 03-7538828