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Press Release

Can-Fite Reports Results of a Phase IIb Clinical Study in Rheumatoid Arthritis with CF101, an A3 Adenosine Receptor Agonist. The Results Support Further Clinical Development of CF101

In a 12 weeks phase IIb study, which tested the safety and efficacy of combined treatment of CF101 with methotrexate in rheumatoid arthritis patients, it was found that the combination has a very good safety profile and was as well tolerated as methotrexate plus placebo through the 12 weeks of dosing. The ACR20 response, which was the primary efficacy end point of the study, showed no difference between the CF101-treated and placebo groups. However, a substantial difference in favor of CF101 was seen in the ACR50, the ACR70 and the EULAR "Good" response measures. The trial also demonstrated that the 1 mg dose of CF101 was the most active dose, an important result for future clinical development.

Can-Fite Biopharma announced today the initial results of its Phase IIb study in 253 rheumatoid arthritis (RA) patients. The study was a double-blind, placebo controlled, 12 weeks study that tested the effect of three doses of CF101 in combination with methotrexate (MTX) in comparison to MTX alone (that is, MTX plus placebo capsules). Preliminary results are being presented herein. The Company continues to conduct a full analysis of safety, efficacy and other data from the study. The preliminary results from this study support Can-Fite's plans to advance its clinical program and to initiate additional clinical studies with CF101.

"Demonstration of definite favorable effects on the signs and symptoms of RA, in conjunction with good tolerability and safety in three months of treatment, represents a major achievement for the CF101 clinical program," commented Michael Silverman, M.D., a Medical Director of the Company. "The preliminary data announced today are encouraging and provide continued support for Can-Fite's plans to move forward in clinical development of CF101 in RA patients", he added.

A total of 239 patients completed 12 weeks of treatment in the trial. The study was conducted at 33 centers in the US, Eastern and Central Europe, and Israel. Patients received either 0.1, 1 or 4 mg of CF101, twice daily, or placebo in combination with weekly MTX.

One goal of the study was to test the safety of CF101. The result demonstrated that the drug had an impressive safety profile and was well tolerated through the 12 weeks of dosing. There was a very low incidence of discontinuations due to adverse events across study groups, with one patient in each of the 0.1 mg, 1 mg and placebo group and 3 patients in the 4 mg group discontinuing prematurely. The overall number of adverse events was small with only one "possibly CF101 related" serious adverse. These safety results corroborate the Company's previous clinical data suggesting that CF101 is a target-specific and well-tolerated drug.

Another goal of the study was to test the efficacy of the combined treatment as compared to placebo. The primary efficacy end point was ACR20. Other efficacy endpoints included ACR50, ACR70 and EULAR response measures.

The ACR20 response showed no difference between the CF101-treated and the placebo groups, all showing a response rate of about 50%. No significant difference was seen between the CF101 treatment groups and placebo. It should be noted that such a high rate of placebo response is much higher than that which could be expected in MTX-failure patients, on the basis of historical data from other clinical studies in similar patient populations. The magnitude of the placebo response as well as the fact that the placebo group accrued responders over the period of the study is felt by the company to be an anomalous and unprecedented outcome. The company believes this finding may result from pharmacologically active components among the excipients that reacted with MTX to yield the observed response. This finding is the basis of a new patent application filed by the Company as further elaborated below.

A marked difference between the CF101-treated and the placebo group was noted in the ACR50 response in all CF101 treatment groups, being 20%, 27% and 19% in the 0.1, 1 and 4 mg groups, respectively, as compared to 13% in the placebo group. The difference between the ACR50 response in the group treated with 1 mg of CF101 and placebo showed a statistical significance of p=0.04[1] and 0.07 by one-side and two-sided analysis, respectively. The ACR70 response was also maximal in the 1 mg treatment group, with 10% of the patients having an ACR70 response as compared to 3% in the placebo group. A marked difference between the treatment group and the placebo was also observed in the EULAR "Good" response in all the three CF101 treatment groups, with the response rates being 6%, 18% and 11% in the 0.1, 1 and 4 mg groups as compared to 5% of the placebo group. The improvement in the 1 mg group showed a statistical significance of p=0.04 by a two-sided analysis.

[1] ITT, LOCF, CRP

Another goal of the study was a selection of a preferential dose of CF101 for future clinical development. Based on the study data the 1 mg dose appears to be the preferential one. This results are in concordance with data from the Company's previous Phase II clinical study in RA patients. This is an important achievement that can advance the future clinical development program of CF101 for RA.

As aforesaid, the results showed an unexpected high response in the placebo group. The placebo formulation includes only the excipients of the CF101 formulation. Initial laboratory tests conducted by the Company showed that that the excipients posses biological activity that may explain the marked effect seen in the patients of the placebo group. The company filed a patent application on the use of these excipients for treating inflammatory diseases.

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.

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