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Press Release

**Can-Fite Initiates Preparatory Work for Psoriasis
Phase III Trial with CF101**

Can-Fite BioPharma, an Israeli Biopharmaceutical company, announced today the initiation of preparatory work for a Phase III trial with CF101 in Psoriasis. This is based on the successful conclusion of a Phase II dose-response clinical study with CF101 to treat patients with moderate to severe Psoriasis; the study successfully met its primary objective of efficacy and safety.

The Phase II study confirmed that CF101 had a clean safety profile, a clear efficacy signal with dose-response data and an excellent therapeutic index. Among the 3 dosages that were used, CF101 at 2 mg had a statistically significant response, according to the Psoriasis Area Severity Index (PASI 75 should this be PASI 50?) score and was the dose with the best performance.

Can Fite will submit an IND to the Dermatology division at the FDA followed by an end of Phase II (EOP2) meeting to discuss registration planning and Phase 3 protocols.

Psoriasis is a skin condition that affects 2% to 3% of the general population. The disease is manifested by scaly plaques on the skin and in the severe form has a major effect on the physical and emotional well-being of the patients. General anti-inflammatory agents such as topical corticosteroids, methotrexate or phototherapy are only partially effective and are limited by safety issues. Recently, novel biologics targeting the underlying immuno-pathogenesis of the disease have been introduced, such as Enbrel, which blocks the activity of the inflammatory cytokine tumor necrosis factor- α (TNF- α). Still, a significant need remains for novel oral and safe drugs for patients who do not respond to existing therapies or for whom these therapies are unsuitable.

The market share for Psoriasis is estimated at US\$ 3.5 billion annually. The oral administration of Can-Fite's CF101, the drug's mechanism of action (suppression of the inflammatory mediator TNF- α) and its excellent safety profile (tested on more than 700 subjects in other trials), support its use for the treatment of psoriasis.

The success in psoriasis adds to the success in a recently announced clinical study in dry eye patients. In both these studies the patients were treated with CF101 as a stand-alone treatment. Psoriasis, as well as dry eye disease are inflammatory diseases. The success in both these studies points to the efficacy of CF101 in treatment of inflammatory diseases, with very large market potential.

Furthermore and most importantly success in these studies validates the technology platform of the company.

CAN-FITE BIOPHARMA LTD 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 Prof. Pnina Fishman, an investigator from Rabin Medical Center, and patent attorney Dr. Ilan Cohn, a senior associate at Reinhold Cohn Patent Attorneys. Prof. Pnina Fishman serves as the CEO of Can-Fite. The Company was founded on the basis of scientific findings made by Prof. Pnina Fishman and focuses on the development of small molecule-based drugs that bind to receptors of cancerous or inflammatory cells and inhibit their development.

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