



## **Interim Analysis Supports Continuation of Can-Fite's Phase 2/3 Psoriasis Clinical Study with CF101**

**Petah Tikva, Israel, October 9, 2012: Can-Fite BioPharma (TASE: CFBI; OTC: CANFY)** announced today the continuation of patient enrollment in its Psoriasis Phase 2/3 clinical study with CF101. This decision follows an interim analysis of safety and efficacy data from the first 103 patients who completed 24 weeks of treatment in the trial. The positive clinical effects of the CF101-2 mg BID dose relative to placebo were observed in a variety of standard psoriasis assessment parameters, with the responses accumulating steadily over the 24-week treatment period. These clinical effect data corroborate the published Phase 2 study and confirm the dose selection, while the favorable safety profile of CF101 further supports its development for the systemic treatment of moderate-to-severe psoriasis. To allow the trial to meet its full objectives, the company therefore intends to complete patient enrollment for this Psoriasis Phase 2/3 clinical study comparing CF101-2 mg BID to placebo, as standalone therapy. The study will include approximately 300 patients overall and is currently conducted in 17 U.S., European and Israeli medical centers.

Psoriasis is a skin condition that affects 2% to 3% of the general population. The psoriasis therapeutic market is estimated at \$3.5 billion annually and is dominated by biological drugs.

**Can-Fite CEO Pnina Fishman, Ph.D.**, commented, "We are pleased to continue the clinical development plan of CF101, a small molecule orally bioavailable drug, based on its encouraging therapeutic index. CF101's anti-inflammatory effect, its well-defined mechanism of action, and the excellent safety profile, all suggest this drug is an attractive candidate for the treatment of psoriasis."

The company also announced that it has listed and begun trading of its American Depository Receipts (ADRs). Shares of the ADRs launched on October 2nd, 2012 on the over-the-counter (OTC) market under the symbol CANFY. The Company's ordinary shares trade on the Tel Aviv Stock Exchange under the symbol CFBI and each ADR share represents 50 ordinary shares.

### **About CF101**

CF101, an A3 adenosine receptor agonist, is a novel, first in class, small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase 2 clinical studies. CF101 is currently developed for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis (Phase 2b) and psoriasis (Phase 2/3). CF101 is



also developed for ophthalmic indications including dry eye syndrome (Phase 3), glaucoma (Phase 2) and Uveitis by OphthaliX (OTC: OPLI), a subsidiary of Can-Fite.

### **About Can-Fite BioPharma Ltd.**

Can-Fite BioPharma Ltd is an Israeli public company, the ordinary shares of which are traded on the Tel Aviv Stock Exchange (TASE: CFBI). American Depository Receipts of the company are traded on the over-the-counter market (OTC: CANFY). The company, which commenced business activity in 2000, was founded by Pnina Fishman, Ph.D., researcher in the Rabin Medical Center, and Ilan Cohn Ph.D., patent attorney and senior partner at Reinhold Cohn Patent Attorneys. Pnina Fishman serves as CEO of the company. The company was founded on the basis of Fishman's scientific findings, and is focused on the development of small molecule orally bioavailable drugs, ligands to the A3 adenosine receptor. The latter mediates anti-inflammatory and anti-cancer effects and is suggested as a biological predictive marker. The company's lead drug, CF101, is in clinical development for the treatment of autoimmune inflammatory diseases. The CF102 drug candidate is being developed for the treatment of liver diseases. Can-Fite has a wealth of clinical experience: to date, more than 700 patients have participated in clinical trials conducted by the company. Can-Fite previously licensed its activity in the ophthalmic field to OphthaliX Inc., in which it holds a controlling interest (OTC: OPLI).

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### **Safe Harbor Statement**

Any statements in this press release that relate to the Company's expectations are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act. The Private Securities Litigation Reform Act of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees. Since this information may involve risks and uncertainties and are subject to change at any time, the Company's actual results may differ materially from expected results. Additional risks associated with Can-Fite's business can be found in its periodic filings with the Tel Aviv Stock Exchange.