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Poster presentation

Clinical Efficacy by Intratumoral Injection of DNA Encoding Human Interleukin-12 in Metastatic Melanoma Patients

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Plasmid DNA encoding human Interleukin-12 (IL-12) was produced under GMP conditions and injected into lesions of nine patients with malignant melanoma (stage IV) previously treated with both, standard and non-standard therapies. The treatment was based on efficacy in preclinical studies with melanoma in mice and gray horses. The DNA was applied in cycles, three injections per cycle, up to seven cycles. Three therapy arms comprised low (2 mg), medium (4 mg) and high (10 to 20 mg) amounts of total DNA. The therapy was well tolerated. Three out of nine patients experienced a clinical response, 2 SD and 1 CR. One patient receiving a low dose of DNA experienced a long-lasting stabilization of the disease for more than three years, while the other two responders received high doses of DNA. All patients but one (P9) experienced a transient response at the intratumoral injection site. Immunohistochemical staining of responders showed local reduction of angiogenesis and lymphocyte infiltrations. All patients, in particular the responders (P3, P7, and P8) exhibited an antigen-specific immune response against MAGE-1 and MART-1. Biopsies of responders showed some increase of IL-12, IP-10 and IFN-γ. (Hu. Gene Ther. 16, 35 (2005)). Combinations of IL-12 DNA with other therapies show significant increase of efficacy in preclinical studies and will be discussed.