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Alpha DaRT: Revolutionary Alpha-Emitters Brachytherapy

Diffusing Alpha-emitters Radiation Therapy ('Alpha DaRT') is a revolutionary new cancer-treatment modality, which enables –for the first time - the treatment of solid tumors by alpha particles. The basic idea is to insert into the tumor an array of implantable seeds, whose surface is embedded with a low activity of radium 224. Each seed continuously emits into the tumor, by recoil, a chain of short-lived alpha emitting atoms (progeny of radium) which spread by diffusion and convection over several mm around it, creating a continuous "kill region"of high alpha-particle dose. After many years of basic work on the technology and associated physics, as well as an extensive campaign of preclinical studies in mice, Alpha DaRT has recently entered clinical trials, in the framework of a new company, Alpha TAU Medical Ltd.

The first trial, in Rabin Medical Center (Israel), focuses on recurrent skin and oral cavity squamous cell carcinoma, and tumor size < 5 centimeters in the longest diameter. So far, 15 of the enrolled patients have completed follow-up. Tumor locations included the chin, ear, tongue, lip, nose, forehead, scalp and parotid skin areas. Treatment was delivered based on a CT-simulation pre-treatment plan. DaRT seeds were inserted under local anesthesia using a specially designed applicator. The seeds (1 cm long and 0.7 mm in diameter) each carrying an activity of 2 μCi 224Ra were placed 5-6 millimeters from each other, based on a DaRT-specific dosimetry model. The total 224Ra activity administered was ~5 μCi per gram of tumor. Two to four weeks after implantation the seeds were removed, and six weeks after treatment CT was performed to assess the effect of treatment. Blood tests and urinalysis were performed during the treatment. The number of DaRT seeds inserted into the tumor was in the range of 7-169 seeds, and treatment duration was 14 to 26 days.

Initial efficacy results for a single application of DaRT seeds, for 15 subjects who have reached the study endpoint, are highly promising: eleven subjects (11/15, 73%) had a Complete Response to the treatment and four (4/15, 27%) had Partial Response (substantial reduction in tumor volume). The treatment was shown to be safe for both the patient and medical staff. Local side effects of the treatment were minimal, amounting to erythema, swelling and mild to moderate pain in the insertion area, which resolved either by the time the seeds were removed or shortly after. Radioactivity measurements of 212Pb in the blood were consistent with a biokinetic model of DaRT, which predicts negligible dose levels to distant organs. No clinically significant abnormal blood or urine lab results, or clinically significant changes in vital signs were observed.

Based on the successful outcomes of the first clinical trial, clinical protocols are in preparation for various indications with leading research centers worldwide, including cutaneous and mucosal neoplasia, neoadjuvant and recurrent rectal cancer, recurrent prostate cancer, inoperable breast cancer, recurrent gynecological cancer, sarcoma and pancreatic cancer.

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