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A novel potential therapy for vascular diseases: Dendritic cells direct pro-angiogenic stimulation of autologous blood-derived stem/progenitor cells

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Background: Vascular diseases including cardiovascular and peripheral vascular are a major cause of morbidity and mortality worldwide. Critical Limb Ischemia (CLI), the most serious form of PVD affects >3 Million people. Within 1 year, 25% of patients die and 30% undergo amputation. We describe a novel technology for generating a therapeutic population (BGC101) of enriched endothelial progenitor cells from a patient's standard blood sample, using dendritic cells (DCs) to direct stem/progenitor cell (SPC) activity. This one day culture process produces sufficient numbers of potentially therapeutic SPCs for the treatment of patients with CLI who do not have other viable treatment options. The EnEPC-CLI-01 clinical study aims to assess BGC101 feasibility in treating CLI patients.

Methods & Results: DCs from healthy and diabetic donors were activated with anti-inflammatory and pro-angiogenic molecules. Co-culture for 12-18 hours of activated DCs with SPCs generated $83.7 \pm 7.4 \times 10^6$ BGC101 cells with >97% viability and angiogenic/stemness potential. When administered to nude mice with limb ischemia, BGC101 yielded a high safety profile, improved blood perfusion, capillary density, and limb function within 21 days ($p < 0.0002$). A phase I/IIa Study (open-label in 5 patients followed by randomized placebo-controlled study in 25 patients) is underway. Preliminary results from the first patients demonstrated a high safety profile and promising clinical outcomes.

Conclusions: DCs promote the generation of EnEPC within culture after one day. The resulting, BGC101, a potential for treatment of vascular conditions, including arteriosclerotic heart disease, stroke and peripheral ischemia is now undergoing a phase I/IIa study in CLI patients.

Biography

Yael Porat has obtained PhD in Immunology from Sackler School of Medicine and is the Founder and CEO of BioGenCell, a Biotechnology Company focusing on Stem Cell Therapy and Regenerative Medicine. She previously served as Head of Global Biological Development at Teva Pharmaceuticals and CTO at TheraVita, where she led research on therapies for patients with cardiovascular diseases.

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