Phase I/IIa clinical trial for the treatment of androgenetic alopecia using intradermal injections of cultured autologous dermal sheath cup cells

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Androgenetic alopecia (AGA) is the most common form of hair loss. Previous studies show that cultured hair follicle dermal papilla or dermal sheath cup cells can induce new hair follicle formation and/or regenerate hair growth in various models. We have recently completed a phase I/IIa clinical trial of intradermal injections of cultured autologous dermal sheath cup cells for AGA (NCT01286649). The trial was designed to gather data related to the product's potential efficacy through 24 months post-injection, but was not designed for statistical significance related to any efficacy endpoints. Biopsies from the scalp occiput of ten men and nine women with mild to moderate AGA were processed to isolate dermal sheath cup tissues for subsequent culture using a GMP-manufacturing protocol. Using a randomized, double-blind, placebo-controlled design, subjects received, via a validated semi-automatic injector, autologous, cultured dermal sheath cup cells or vehicle alone in two separate predefined, tattoo-marked, contralateral scalp areas with thinning hair. Subjects returned to the clinic at regular intervals for 5 years for safety evaluation and for efficacy assessments at 6 and 24 months post injection. No serious adverse events were reported over the 5 year follow-up period. For all per-protocol participants, overall stabilization of hair loss was observed at 24 months. The top 10 participants with greater than 5% increase in hair density at 6 months post-injection, demonstrated a sustained response at 24 months averaging a 4.2% increase over baseline hair density. The clinical trial data supports further optimization of autologous dermal sheath cup cell treatment to be evaluated in future phase II clinical trials.