An autologous cell-based treatment for androgenetic alopecia

Phase I/IIa 6-Month Interim Analysis

RepliCel™

Introduction

RepliCel Life Sciences has developed a patented, natural hair cell replication technology for the treatment of androgenetic alopecia (AGA) and general hair loss in men and women. The protocol for RepliCel's TS001-2009 first-in-man clinical study was developed with advice from European Union regulatory authorities responsible for advanced therapy medicinal products (ATMPs). The trial was designed to test the safety and efficacy of RepliCel's technology in men and women with AGA. The protocol, was designed in compliance with International Conference on Harmonisation guidelines for Good Clinical Practice (ICH GCP) based in advice received from the Paul-Ehrlich-Institut; an Agency of the German Federal Ministry of Health. Before study initiation, the protocol underwent thorough scientific and ethical review by the Georgian National Council of Bioethics and approval to conduct the study was granted on Oct, 27, 2010.

Clinical Trial Protocol

Subjects with mild to moderate AGA categorized on the Ludwig Scale (female) or the Norwood scale (male) were enrolled in the study over a 4-month period starting in Dec. 2010. These subjects provided blood samples to confirm their health status and scalp biopsies which were sent to a cGMP-compliant facility with the specific license to manufacture RepliCel's product in Austria. Once the manufacturing process was completed, the 19 subjects returned to the clinic to receive blinded injections of their own (autologous) replicated dermal sheath cup cells (DSCC) in a carrier medium on one part of their scalp, and another injection of carrier medium without replicated cells (placebo) on the other side of their scalp to allow for better assessment of the safety and efficacy of the RepliCel™ technology. The final study participants received injections of hair follicle cells in late August 2011, thus marking the end of the treatment phase of TS001-2009 trial.

In the next stage of the trial, the post-injection follow-up period, subjects return to the clinic for ten follow-up visits over a 24-month period to have their health closely monitored to ensure that there were no adverse effects associated with receiving the injections and to determine the efficacy of hair follicle cell injections at stimulating hair growth.

The primary protocol objective of the study was to assess the local (at treatment sites) safety profile of injections of autologous DSCC at six months post-injection compared to placebo. Secondary protocol objectives were to assess systemic (overall) safety and efficacy (hair growth at treatment sites) at 6 and 24 months post-injection and local safety at 24 months post-injection. The six-month interim analysis was designed to provide the Company with safety information to support the regulatory filing for a Phase IIb clinical trial. These results support the continued development of DSCC for the treatment of AGA.

6-month Interim Analysis Results

- Screened 30 subjects (16 male, 14 female)
- Harvested 25 biopsies (12 male, 13 female)
- 19 subjects injected (10 male, 9 female)
- 3 subjects had to be excluded from efficacy result analysis because their injection products were shipped outside of the temperate range stated in the protocol

Local Tolerance

- The majority of injections were well-tolerated
- 30% of subjects experienced a minor burning sensation related to injections of autologous DSCC
- The majority of these reactions resolved within 24-48 hrs

Systemic Safety

- No serious adverse events reported in first 6 months post-injection
- None of the 25 events reported by 12 subjects were considered related to study injections

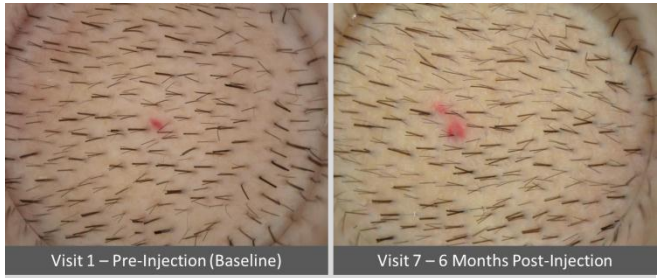
Primary Endpoint of Safety

- No serious adverse events

Secondary Endpoint of Early Efficacy

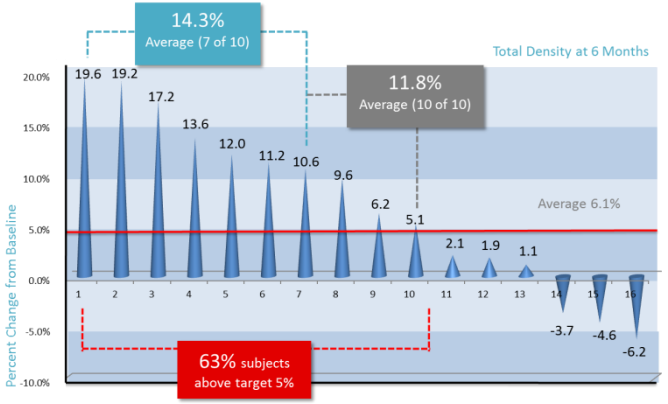
- Significantly more subjects demonstrated a ≥5% increase in hair density at dermal sheath cup cell treated sites vs. control-treated sites (63% vs. 37%)
- 63% of the treated subjects (10 of 16) had ≥5% increase in total hair density (treatment response endpoint)
- 70% of those 10 subjects had ≥10% density growth
  - Including: 19.6%, 19.2%, 17.2%, 13.6%, 12.0%, 11.2% & 10.6%
  - Average = 14.2% for the 7 of 10 subjects ≥10%
  - Average = 11.8% for the 10 of 10 subjects ≥5%
- The average increase from baseline at DSCC-treated sites was 6.1% for patients treated per-protocol

6 Month Post Injection Image from One Patient



Increase in vellus hair density of 24.9%
Increase in terminal hair density of 14.5%
Total hair density increased by 19.2%
Cumulative thickness per area increased by 15.4%
Tattoo refresh at 6 months

Total Hair Density - Percent Change from Baseline



Positive and negative data direct process improvement

Conclusion

Six-month interim analysis of data revealed that the RepliCel™ treatment is safe and effective. This data, along with indication of a positive density response, allows the Company to move forward with a Phase IIb dosing trial. RepliCel is working with European regulators to finalize protocols for the Phase IIb clinical trial application, expected to commence in late 2012. The Phase IIb trial will be designed to optimize treatment regimen for hair growth. Several different treatment regimens will be tested, including different concentrations of cells and different treatment schedules, including single and repeat injections.