Subject: Intercytex Update 26.03.09
Posted by benutzer81 on Thu, 26 Mar 2009 07:58:27 GMT
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Zitat:ICX-TRC
Product description
ICX-TRC consists of a suspension of autologous dermal papilla (DP) cells. These cells are able to stimulate the generation of new hairs when injected into the scalp in close proximity to the epidermal cells
which generate the hair. It is intended that ICX-TRC will be used by specialists in hair transplant centres,
dermatologists and plastic surgeons to treat patients with hair thinning or hair loss.

Clinical development
We have now completed our Phase II study, which was conducted by Dr Bessam Farjo in Manchester, to examine different ways to deliver the DP cells. DP cells naturally reside at the base of all
hair follicles and are known to control the growth and cycling of hair. It has been known by scientists for
many years that these cells can also interact with epidermal cells in the skin and induce them to form new
hairs. For this to occur however, the DP cells need to be placed close to the epidermal cells which in turn
need to be in a correct inducible state to respond to the DP signals.
This trial was designed to examine the effect of different DP delivery techniques and methods to ensure
that the epidermal cells were in the correct state to respond to the signals and produce new hairs.

was
photographed at the end of the study. Subjects were also injected in a smaller area, divided into two
sections - counts were obtained by shaving and photographing the two small sections of scalp,

cell
suspension and then applying a specialised image analysis system to provide a total hair count. In these small sections, all 19 subjects in the trial were treated using a range of injection and scalp prestimulation
techniques; the first 6 subjects were injected without stimulation of the scalp. In the
remaining 13 subjects the resident hair producing (epithelial) cells were stimulated at the time of delivery of the DP cells in one of the two treatment sites.
13 subjects completed the 48-week trial with 6 subjects lost to follow-up. Of the 13 subjects completing
the trial the data showed that:

· 65% (11/17) of the treated sites in the non-stimulated group responded to the treatment by increasing numbers of hairs of all sizes
· 71% (12/17) of the treated sites in the non-stimulated group responded to the treatment by

increasing numbers of hairs over 30 micron in diameter
· 78% (7/9) of the treated sites in the stimulated group responded to the treatment by increasing numbers of hairs of all sizes
· 100% (9/9) of the treated sites in the stimulated group responded to the treatment by increasing numbers of hairs over 30 micron in diameter
· The overall take rate (number of hairs produced per 100 injections) in the stimulated areas was
o 40% (n=6) for hairs of all sizes
o 18% (n=6) for hairs over 30 micron in diameter

The larger (900 injection) area photographs have not yet been analysed.
These data are consistent with the interim data reported last September and further confirm the hypothesis that new hair production is improved by pre-stimulation of the scalp, leading to an interaction between the injected cells and the resident hair producing cells.

Dr Bessam Farjo, the Principal Investigator for this study, said “We have learned a lot from this trial,
including the different ways in which these cells can be delivered and that it is possible to do one thousand of these injections in a relatively short period of time and at little discomfort to the patient. I
am very encouraged by this data both in the increase in the total number of hairs in the treated site but
more importantly by the increase in thicker hairs, those over 30 micron.”
Further results of the trial will be presented later in the year.

Commercial opportunity
ICX-TRC overcomes one of the principal drawbacks of conventional transplants which is that the outcome is limited by the amount of donor hair available. By using the Intercytex cell therapy technique
almost limitless hair regeneration is possible in a less invasive procedure. Furthermore, treatment can
commence early on in the hair loss process with retreatment available in subsequent years. The barrier
to commercial success for ICX-TRC is relatively low, being the ability to increase hair count in transplanted or thinning areas.
We believe the continued development of ICX-TRC would best be carried out in partnership with a specialist in the aesthetics field. We do not intend to finance the continuation of clinical and commercial
development of ICX-TRC beyond the current Phase II trial and shall seek to sign a partner when we have
the complete data package from this trial. Intercytex has granted Bosley, the largest chain of hair transplant clinics in the US, an option to negotiate distribution rights to the product.

Intellectual Property
We have split our cell delivery patent application into three separate applications in the US reflecting
additional techniques that are being developed. We have also filed a patent application relating to our

observation that epidermal stimulation pre-treatment appears to enhance hair follicle formation. Two
other previously filed patent applications relating to the method of culturing the dermal papilla cells have
been published and are undergoing international examination.

Link:

http://www.intercytex.com/icx/news/releases/2009/2009-03-26/ 2009-03-26.pdf

Die daten sind nicht mal so übel, es fehlen jedoch fotos.