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Media information

Modex updates on internal programs - EpiDex™ and BioDelivery

Modex Therapeutics Ltd (SWX New Market: MDXN) provided today an update on its two principal programs: the EpiDex™ Phase II clinical trial and the BioDelivery program.

The EpiDex™ Phase II clinical trial

The ongoing trial is being conducted at twelve centers in Europe, four in Switzerland and eight in Germany. The trial involves the treatment of 80 patients with hard to heal leg ulcers who would normally be treated by a surgical skin graft. As planned, the enrollment of the 80 patients was completed in May of this year.

EpiDex™ is an autologous epidermal skin equivalent that is grown directly from stem and pre-cursor cells derived from hair taken directly from a patient in a non-surgical procedure. The EpiDex™ application is a simple procedure that can be carried out in the doctor's office, without the need for hospital admission. On the other hand, the surgical skin graft comprises a section of epidermis surgically removed from another area of the patients' body that is then grafted onto a chronic non-healing wound.

The EpiDex™ randomized Phase II clinical study compares EpiDex™, the tissue engineered autologous skin product developed by Modex, to the surgical split thickness mesh graft currently regarded as the gold standard for the treatment of very hard to heal chronic leg ulcers.

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The 3 end points of the trial are as follows:

(a) The proportion of patients whose wound is completely closed 12 weeks after treatment initiation
(b) The decrease of the skin ulcer surface area over the 12 week period i.e. the rate of wound closure
(c) Safety and tolerability of EpiDex™

The preliminary data on the first 36 evaluable patients who have completed the first 12 weeks of the study is as follows:

1. Complete wound closure
   At 12 weeks, the preliminary results demonstrated that the EpiDex™ skin equivalent was as effective as the surgical procedure of the split skin mesh grafting.

2. Rate of wound closure
   All patients who had received EpiDex™ showed a significant clinical reduction in skin ulcer surface area. For those patients who received the split skin mesh graft treatment and who did not have their wound closed at 12 weeks, no clear reduction in the skin ulcer surface area was observed, in fact 18% of these patients experienced an increase in wound size.

3. Safety
   EpiDex™ was well tolerated and safe. The investigators reported no unexpected safety concerns.

In parallel a pharmoeconomic assessment is underway, and preliminary data suggests that EpiDex™ provides cost savings of at least 30% over the split skin mesh graft treatment.

"Although preliminary data should be interpreted with caution, the data suggests that EpiDex™ has similar efficacy to the surgical split skin mesh graft and therefore may be a viable alternative for the treatment of recalcitrant chronic skin ulcers" noted Dr René Goedkoop, Medical Director of Modex. "We are looking forward to confirm these results with the complete 80 patient data set for the Phase II trial, which will be fully analyzed by October 2001".

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BioDelivery program

Modex has decided to switch the hollow fiber device currently used for its BioDelivery programs for a larger proprietary device, known as a flat sheet.

The flat sheet device, which measures between 5mm and 20mm in diameter, and which can hold up to 10 time more cells than the hollow fiber, will provide Modex with a greater delivery range with respect to its chosen programs.

The flat sheet device will need to be further tested and validated before entering the EPO Phase II trial, which will result in an approximate 12-month delay. These steps will include finalizing the manufacturing process as well as conducting toxicity and safety studies in human volunteers. Modex will be assisted in this validation work by a Swiss university medical center.

"We are very encouraged by the interim positive results of the EpiDex™ Phase II clinical trial" commented Dr Jacques Essinger, CEO of Modex. "The final results will establish Modex with a privileged position from which to initiate the development of new wound care products. At the same time, we are confident that the switch of the BioDelivery device design is an appropriate change which will increase the therapeutic range of the BioDelivery platform".

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Further information regarding Modex can be found on the website www.mdxn.ch as well as further information regarding EpiDex™ on the website www.epidex.com.

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A leader in the field of T3R

Modex Therapeutics Ltd is a Swiss biotechnology company, based in Lausanne with a focus on tissue repair, replacement and regeneration (T3R). T3R heralds a new era for healthcare, aiming at regenerating cells for the repair or replacement of deficient tissue. Modex currently focuses its development work on two cell-derived products and technologies:

EpiDex™ is a skin equivalent product in Phase II trials that is derived from stem and precursor cells found in the human hair follicle.

BioDelivery proprietary technology uses immortalized fibroblast cells to continuously deliver therapeutic proteins and has several candidates in various stages of development.

The strategy of the company is to in-license advanced and promising T3R technologies, to drive them to a mature stage, and to realize the added value by licensing or selling the developed products to pharmaceutical, biotechnology or medical device companies. Modex Therapeutics (MDXN) has been listed on the SWX New Market since June 2000.