Press release

Modex announces final positive results from its Phase II clinical trial for EpiDex™.

Company presents updated business strategy focusing on Dermatology.

Lausanne, Switzerland, October 8, 2001 – Modex Therapeutics Ltd (SWX New Market: MDXN) announced today positive final results from its EpiDex™ Phase II clinical trial. These positive results confirm the interim results announced in June and further support the observations of dermatologists in Switzerland and Germany where EpiDex™ is already being sold for the treatment of hard-to-heal chronic skin ulcers.

The EpiDex™ randomized Phase II clinical trial compared EpiDex™, an autologous skin product developed by Modex, to the surgical split thickness mesh graft currently regarded as the gold standard for the treatment of hard-to-heal chronic leg ulcers.

The trial was conducted at twelve centers in Europe, four in Switzerland and eight in Germany, and assessed results from 77 evaluable patients with hard-to-heal leg ulcers. No other cell-based wound healing product has ever been directly compared to the surgical skin graft in a clinical trial. The trial was deliberately designed to recruit patients requiring a surgical skin graft.

The 3 end points of the trial were as follows :

(a) The proportion of patients whose wound was completely closed 12 weeks after the start of treatment

(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 data on the 77 evaluable patients are as follows:

1. Complete wound closure

At 12 weeks, the results demonstrated that EpiDex™ was as effective as the surgical procedure of split skin mesh grafting. The proportion of patients with complete closure of their hard-to-heal chronic skin ulcers after 12 weeks was statistically the same at 33% for EpiDex™ and 41% for the split mesh graft, respectively (*P* = 0.4). The two treatments were well balanced in terms of baseline characteristics (age, ulcer surface, venous insufficiency)

2. Rate of wound closure

78% of all patients who received EpiDex™ showed a significant reduction in skin ulcer surface area compared to 72% in all split skin mesh grafted patients. A significant effect is defined as a reduction in skin ulcer surface area greater than 50%. Those patients who received the split skin mesh graft without their wound closing at 12 weeks demonstrated no significant reduction in the skin ulcer surface area. In addition, more than twice as many treatment failures were observed in the split mesh graft group (19%) compared to the EpiDex™-treated group (7%). Patients for whom the split mesh graft treatment failed experienced an increase in wound size, whereas this did not occur for EpiDex™-treated patients.

3. Safety

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

Furthermore, the number of patients who decided not to undergo the assigned treatment after the un-blinding was 8 for the surgical skin graft compared to none in the EpiDex™ group. This demonstrates the reluctance of patients to enter the surgery for the split mesh graft treatment and provides evidence that the ambulatory procedure of EpiDex™ treatment is the preferred treatment of choice for the patient.

A recent pharmacoeconomic assessment conducted in two centres suggests that EpiDex™ provides cost savings of at least 30% over the split skin mesh graft treatment.

"The data demonstrate that EpiDex™ has equivalent efficacy to the surgical split skin mesh graft and since it is not invasive, it should become the preferred alternative for the treatment of recalcitrant chronic skin ulcers," commented Dr René Goedkoop, Head of Clinical Development at Modex.

“We are delighted by the positive conclusion of our EpiDex™ clinical trial,” commented Dr Jacques Essinger, Chief Executive Officer of Modex. “These results demonstrate that EpiDex™ is the superior product for the treatment of hard-to-heal skin ulcers. We are now in a strong position to extend the marketing launch of EpiDex™ in Europe and to prepare the Investigational Device Exemption (IDE) filing for the USA with a view to starting a clinical trial there in 2002.” He added: “These results firmly position Modex as a leading company in chronic wound care and provide a solid foundation to initiate the development of new products in wound care and skin disease”.

EpiDex™ is an autologous epidermal skin equivalent grown directly from adult stem and precursor cells derived from hair plucked from the patient in a non-surgical procedure. The EpiDex™ application is a procedure that can be carried out in the doctor's office, without the need for hospital admission. The surgical skin graft, on the other hand, requires hospitalisation and involves surgical removal of a section of epidermis from another area of the patient’s body which is then grafted onto the chronic non-healing wound.

Today, Modex will present the results of the EpiDex™ clinical trial to media, analysts and investors at the Swiss Stock Exchange in Zurich. The Company will also present its marketing and sales plans for EpiDex™ and its business strategy regarding the Company’s focus on the Dermatology market.

A leader in biotechnology solutions for dermatology

Modex Therapeutics Ltd is a Swiss biotechnology company founded in 1996 that is developing therapeutic products for the treatment of skin wounds and skin diseases. Recognizing new opportunities in dermatology, Modex is expanding its product pipeline to include new therapeutic agents for the treatment of a wide range of skin diseases. Core competences in biotechnology and strengths in clinical development enable Modex to develop innovative products for the treatment of skin disorders and disease. The goal is to become a leading dermatology company by progressively establishing a product pipeline for diverse indications.

Modex' first product, EpiDex™, is a human skin equivalent derived from the adult stem and precursor cells found in the patient's own hair follicles ("hair to skin"). The EpiDex™ product has been successfully compared in a head-to-head clinical trial with human autologous skin. The clinical trial data showed, for the first time, that an artificially cultured epidermal product grown from the hair can be superior to the transplantation of skin from another area of the patient's body. These clinical trial data support the claim that EpiDex™ is the premium product of choice for the treatment of hard-to-heal skin ulcers.

Modex is building a sustainable business that offers a complete range of innovative therapeutic solutions in dermatology through its existing development pipeline and by growing its portfolio of superior technologies. Registered shares of Modex Therapeutics (MDXN) are traded on the SWX New Market.

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