Epidermolysis Bullosa Wound Healing Study

ONLY 6 SLOTS REMAIN

A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study of the Safety and Efficacy of Thymosin Beta 4 in the Treatment of Patients with Epidermolysis Bullosa.

RegeneRx Biopharmaceuticals, Inc. (www.regenerx.com) continues to recruit participants for its Phase 2 clinical trial to test the safety and wound healing properties of Thymosin Beta 4 (Tß4) in EB wounds. The purpose of this research study is to find a way to help EB wounds heal better and faster. Quicker healing will decrease pain and scarring, decrease the cost of bandages and improve the quality of life for EB patients.

Patients with Junctional or Dystrophic EB are being sought for a wound healing study to evaluate the safety and effectiveness of Tß4, which is a synthetic copy of the naturally-occurring substance found in most human cells and tissues. It represents a new class of wound healing medicine. This and other studies, if successful, will be used to support the marketing approval of Tß4 by the FDA.

In the form of a gel the study medication (Tß4 or Placebo) will be placed once a day on a single wound (a sore selected by the doctor for treatment). It will be used each day until the lesion heals or for up to 8 weeks, whichever comes first. Visits to the Study Doctor will be required every other week, for a total of 7 study visits, and two follow up phone calls. There is a travel expense reimbursement policy in place to ease patient participation. Listed here are some of the criteria patients must meet to be eligible for this study:

- Junctional EB = Age 2 or older
- Dystrophic EB = 18 months or older
- Lesion to be treated must be:
  - located on a limb or the trunk
  - present for 14-60 days
  - 5cm² to 50cm²
  - Clear of infection
- No investigational drug within 30 days of study entry
- No immunotherapy or cytotoxic chemotherapy within 60 days of study entry
- No current or former malignancy, including SCC
- No Diabetes Mellitus
- Not pregnant or breastfeeding
- Steps to prevent pregnancy in females of childbearing potential
- Other health issues
- Availability for study visits

The study is being conducted by the following physicians:

- Elizabeth Alvarez Connelly MD, University of Miami, Miami FL – 305-243-8485
- Lawrence Eichenfield MD, Rady Children’s Hospital, San Diego CA – 858-576-1700 x 4295
- Jo-David Fine, Vanderbilt University, Nashville TN – 615-936-1133
- Mary Gail Mercurio MD, University of Rochester, Rochester NY – 585-273-2909
- Kim Morel MD, Columbia University, New York NY – 212-305-6953
- Amy Paller MD, Children’s Memorial Hospital, Chicago IL – 773-327-3326
- Thomas Serena MD, Select Specialty, Erie PA – 814-452-7878
- Amy Theos MD, University of Alabama Birmingham, Birmingham AL – 205-502-9960
- Karen Wiss MD, Univ of MA Hahnemann Campus, Worcester MA – 508-856-2908

For more information about the study and how to participate, you may talk with your Doctor or Madeline Weiner, RN, RegeneRx Biopharmaceuticals, Inc. at madeline.weiner@mindspring.com