

## **Additional Study Sites Added for EB Wound Healing Study**

*As part of DebRA's ongoing commitment to keep patients apprised of the latest information, DebRA has agreed to provide the following for information purposes only.*

The official title of the study is *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](http://www.regenerx.com)) is still recruiting participants for its Phase 2 clinical trial to test the safety and wound healing properties of Thymosin Beta 4 (T $\beta$ 4) in EB wounds. The study is open to people age two and older with Junctional or Dystrophic EB.

In response to patients who would like to participate at local facilities, RegeneRx has expanded the number of physician investigators throughout the US. Additionally, RegeneRx has a travel expense reimbursement policy in place to facilitate patient participation in the study.

The following physicians are participating in the study:

- Jo-David Fine MD, MPH, Vanderbilt University, **Nashville TN**
- Anna Bruckner MD, Stanford University, **Stanford CA**
- Moise Levy MD, Texas Children's Hospital, **Houston TX**
- Kim Morel MD, Columbia University, **New York NY**
- Tor Shwayder MD, Henry Ford Medical Center, **Detroit MI**
- Karen Wiss MD and Amit Garg MD, University of Mass at Hahnemann Campus, **Worcester MA**
- Elizabeth Alvarez Connelly MD, University of Miami, **Miami FL**
- Amy Paller MD, Children's Memorial Hospital, **Chicago IL**
- Amy Theos MD, University of Alabama Birmingham, **Birmingham AB**
- Susan Bayliss MD, St. Louis Children's Hospital, **St. Louis MO**
- Jon Dyer MD, University of Missouri Columbia, **Columbia MO**
- David Pariser MD, Virginia Clinical Research, Inc., **Norfolk VA**
- Mary Gail Mercurio MD, University of Rochester, **Rochester NY**

Plans are underway to add additional study sites in Pennsylvania and Southern California.

The study medication (T $\beta$ 4 or Placebo) is supplied as a gel and will be applied once daily to a single lesion (a sore selected by the physician investigator for treatment evaluation). Study medication will be applied daily until the lesion completely heals or for up to fifty-six days, whichever comes first. Visits will be required weekly for the first month of the study and then biweekly.

T $\beta$ 4 is a naturally occurring substance present in virtually all human cells. It represents a new class of wound healing drug. A key mechanism of action is T $\beta$ 4's ability to regulate the cell-building protein, actin, a vital component of cell structure. Additionally, it has been reported that T $\beta$ 4 directly influences the production of laminin-5, a protein,

important to the wound healing process because it is known to promote cell migration and adhesion.

Listed here are some of the criteria patients must meet in order to be eligible to participate in this study:

- Age 2 or older
- Junctional or Dystrophic EB:
- Lesion to be treated must be:
  - located on a limb or the trunk
  - 14-60 day duration
  - 5cm<sup>2</sup> to 50cm<sup>2</sup>
  - Clear of infection
- No investigational drug within 30 days
- No immunotherapy or cytotoxic chemotherapy within 60 days
- No systemic or topical steroidal therapy within 30 days (except inhaled steroids)
- No systemic antibiotics within 7 days
- No current or former malignancy, including SCC
- No Diabetes Mellitus
- Not pregnant or breastfeeding

Additional considerations:

- Females of childbearing potential
- Other health issues
- Availability for study visits

For more information about the study and how to participate, you may contact one of the physicians listed above or Madeline Weiner, RN, RegeneRx Biopharmaceuticals Inc., at 919-929-1855 or [madeline.weiner@mindspring.com](mailto:madeline.weiner@mindspring.com).