



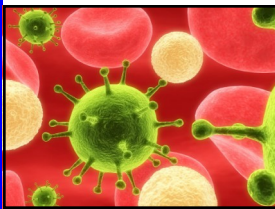
Hemangioma



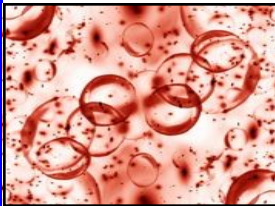
Gene Therapy



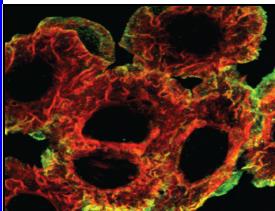
Bioengineered Skin



Antimicrobials



Angiogenesis



Growth Factors

# NewBridge

## MEDICAL RESEARCH

volume 7

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### RESEARCH AND STUDIES UPDATE

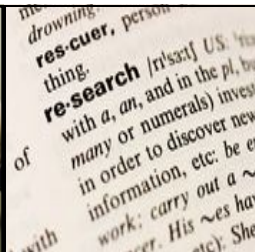
- [NEXAGON STUDY FEATURED IN USA TODAY](#)  
*Early results in Nexagon study promising*
- [PHASE II CODA TRIAL COMPLETED](#)  
*Safety and Efficacy trials completed all in NewBridge Centers*
- [GLOBAL OUTREACH](#)  
*Haiti, Rwanda, Cambodia. Volunteers still needed*
- [RESEARCH TRAINING COURSE ESTABLISHED](#)  
*Training in new course scheduled for Jan, 2011*
- [DEVO PIVOTAL TRIAL EXPANDED](#)  
*ACMH added as a Study Center*
- [MEETING AND LECTURE SCHEDULE](#)
- [US BIOTEST UNDERWAY](#)  
*Trial started at Warren General Hospital*
- [PRODUCT DEVELOPMENT](#)  
*Assisting companies develop new devices and pharmaceuticals*
- [POWER PANEL DOCUMENT GOING FORWARD](#)  
*Guidance document for wound healing research continuing*



Medical Devices



Animal Studies



Pediatric Wounds



Hyperbaric Oxygen



## Nexagon Study Featured in USA Today

LONDON (AP)— For three years, Connie McPherson had debilitating leg ulcers that were so painful she sometimes couldn't sleep. Despite repeated surgery, antibiotics, steroids and other treatments, nothing helped.

Then last year, she took part in a trial for a new gel aimed at chronic wounds.

"It was the answer to my prayers," said McPherson, 58, a real estate agent in Tulsa, Oklahoma. Within weeks, McPherson said the ulcer treated was completely healed. "I tried everything possible and this is the only thing that worked."

The gel used to treat McPherson was developed by a team led by David Becker, a professor of cell and developmental biology at University College London. The gel, named Nexagon, works by interrupting how cells communicate and prevents the production of a protein that blocks healing. That allows cells to move faster to the wound to begin healing it.

In an early study on leg ulcers, scientists at the company Becker co-founded to develop the gel found that after four weeks, the number of people with completely healed ulcers was five times higher in patients who got the gel versus those who didn't. The average leg ulcer takes up to six months to heal and 60 percent of patients get repeated ulcers.

Other experts said the gel appeared promising. "It looks like the gel has a good effect in getting the outer layer (of skin) to restore itself," said Phil Stephens, head of tissue engineering and repair at Cardiff University. Stephens is not linked to Becker's research.

"This gel has the potential to do a lot of good," said Dr. Thomas Serena, founder and director of the Penn North Centers for Advanced Wound Care [NewBridge Medical Research Corp] in Pennsylvania. Serena has no financial ties to Nexagon, but is one of the primary investigators for a U.S. trial of the product.

Another study is planned soon which experts said should answer more questions like the right dosage of the gel and any side effects.

*"This gel has the potential to do a lot of good," said Dr. Thomas Serena, founder and director of the Penn North Centers for Advanced Wound Care*

*[ NewBridge Medical Research Corp ] in Pennsylvania.*

## PHASE II CODA TRIAL COMPLETED

The CoDa phase II trial investigated the safety and efficacy of Nexagon® in promoting the healing of venous leg ulcers. Nexagon® blocks the expression of Connexin 43 which is thought to inhibit wound healing. Dr. Serena is scheduled to present the trial results at next year's annual SAWC/WHS meeting.

One of the unique aspects of this trial was the collaboration between the New Bridge sites and investigational centers in New Zealand. Approximately one half of the patients were enrolled by sites under the direction of NewBridge Medical Research. The remainder were enrolled by sites throughout New Zealand. This was the first example of NewBridge Medical Research-managed centers joining together to conduct entire clinical trials. Preparations are underway for the next phase II clinical trial with Nexagon.®



## GLOBAL OUTREACH (HAITI, RWANDA, CAMBODIA)

In 2010 New Bridge participated in the relief efforts in Haiti and continued a long time commitment to research into the treatment and prevention of HIV/AIDS in Africa. After his initial trip to Kigali Rwanda, Dr. Serena is convinced that volunteers will be needed for years to come. Looking forward to later this year a return trip to Cambodia is under consideration as well as several other medical missions. New Bridge is looking for volunteers to join the effort. Interested clinicians should contact Dr. Serena (814) 688-4000).

## RESEARCH TRAINING COURSE ESTABLISHED

There is a large unmet need for investigators in wound healing research. However, the regulatory hurdles and lack of formal training have prevented interested clinicians from participating in clinical research. Moreover, research in chronic wounds differs substantially from typical pharmaceutical clinical trials. This course will address the unique skills required to conduct studies in the field of wound care. It will be required for any of the Serena Group sites to join ongoing trials. If you are interested in research please plan on joining us in January of 2011. Meeting brochures will be available in August 2010

### **Course Objectives:**

- To educate investigators, nurses and staff in the unique challenges in conducting research in the field of wound healing.
- To teach Good Clinical Practices to all participants.
- To provide practical training in procedures associated with wound healing trials, such as wound assessment and debridement.
- To introduce the concept of comparative effectiveness research (CER).

*For more information, please contact:*

*Rachel Thayer at (814) 230-7000 Ext 101*



## DEVO PIVOTAL TRIAL EXPANDED

The DEVO clinical trial testing the safety and efficacy of Dermagraft vs. standard of care in the treatment of venous leg ulcers has expanded to The Snyder Institute for Vascular Health at Armstrong Memorial County Hospital. The trial is hoping to complete enrollment by 2011. Adding ACMH's experienced staff will boost enrollment from the New Bridge site. Heather Connell has completed training and has scheduled patients starting August 10. **With ACMH as a satellite, New Bridge will be the highest enrolling site in the world.**

### MEETING AND LECTURE SCHEDULE

- Annual Meeting of The Mexican Wound Healing Society. Acapulco. September 2-5.  
Five lectures on topics ranging from bioengineered skin to establishing a center of excellence in wound healing .
- Clinical Symposium on Advances in Skin and Wound Care, Orlando September 30-October 3.  
Assessment of the microcirculation.  
Wound Healing on a Cellular Level.
- American College of Hyperbaric Medicine Annual Meeting Milwaukee October 15-16.  
Four lectures on Hyperbaric Medicine topics.
- 6th Annual Wound Healing Symposium, Somersworth NH. October 21.  
Evidence for Hyperbaric Medicine .
- Overlook Hospital Symposium. October 29.  
The most recent developments in Hyperbaric Medicine.

### UPCOMING PUBLICATIONS

- A publication on the use of MIST in combination with E/Stim. is scheduled for the October issue of *Advances in Wound Care* based on studies conducted at the Snyder Institute.
- Connexin 43 article in *Journal of Experimental Medicine*.

## PRODUCT DEVELOPMENT

New Bridge continues to assist companies in the development and testing of new medical devices and pharmaceuticals. For example, Enzysurge is working closely with our clinics in the development of its streaming technology. Clinical trial planning is underway.

## POWER PANEL

The **POWER** ( Panel On Wound Care Evidenced-based Research) **PANEL** a national group of thought leaders in Wound Healing Research, under the leadership of its Chairman, Dr. Thomas Serena MD FACS, continues its work on a guidance document for the conduct of research in wound healing. The purpose of the consensus document is to guide sponsors and investigators in conducting methodologically sound clinical research. The second round of a Delphi survey has been sent to over 100 experts in the field. “We hope to have a manuscript ready for publication later this year,” commented Dr. Serena.

## US BIOTEST UNDERWAY

The US Biotest Diabetic Foot Ulcer trial is underway at the Warren General Hospital Wound and Hyperbaric center. This trial sponsored by the National Institutes of Health (NIH) is examining the efficacy of a novel pharmaceutical gel.

## ABOUT US

NewBridge Medical Research has conducted more than 50 clinical trials, ranging from novel antibiotics to bioengineered skin, growth factors, and platelet gels.

NewBridge is recognized internationally as being in the forefront of wound healing research. Our large patient volume affords us the ability to conduct clinical trials for all of the major pharmaceutical and device companies.

We conduct research at all of our wound care clinics, which has resulted in more than 75 published papers and over 175 presentations worldwide. Our clinical trials make novel treatments available to a patient population with diabetes and venous insufficiency while providing a modest revenue stream for our hospitals.

NewBridge is incorporated as a 501(c)3 non-profit corporation dedicated solely to improving the science of wound care in the US and throughout the world.

For additional information regarding research and clinical trials, please contact us at [www.serenagroup.net](http://www.serenagroup.net) or (814) 688-4000

**NewBridge**  
MEDICAL RESEARCH

**SerenaGroup**

building the nation's leading wound care team.

[www.serenagroup.net](http://www.serenagroup.net)