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**Contact:** Robert Bancroft  
Executive Vice President, Strategic and Commercial Development  
rob.bancroft@healthpointbio.com  
1.800.441.8227

**POSITIVE RESULTS FOR PHASE IIb TRIAL OF UNIQUE CELL-BASED  
THERAPY IN VENOUS LEG ULCERS**

***Robert Kirsner, MD, PhD, to Present Results at American College of  
Wound Healing and Tissue Repair***

**FORT WORTH, TX, AUGUST 4, 2011** – Healthpoint Biotherapeutics today announced positive topline results for its Phase IIb clinical trial investigating the efficacy of HP802-247 in venous leg ulcers. HP802-247 is an investigational allogeneic living cell suspension containing keratinocytes and fibroblasts. The study was designed to determine the potential effectiveness of two cell concentrations and two dosing frequencies of HP802-247, when combined with standard care, compared to control plus standard care, in healing venous leg ulcers over a 12-week treatment period. The control in this trial was the self-assembling fibrin matrix that is part of the HP802-247 formulation, and which creates a provisional extracellular matrix in the wound.

Overall, HP802-247 achieved statistical significance, as compared with control plus standard care, in both the primary and secondary endpoints: average percent change from baseline in the target wound area over the 12-week double-blind treatment ( $P=0.04$ ), and time in days to complete wound closure from baseline ( $P=0.02$ ). Statistical significance was also achieved for percent change from baseline in the target wound area at 10 of the 12 double-blind evaluation visits ( $P<0.05$ ), and proportion of complete wound closure at 9 of the 12 double-blind evaluation visits ( $P=0.03$ ). HP802-247 appears to be generally safe and well tolerated, with the safety profile of the active groups being similar to placebo.

“Approximately 70% of subjects in the active treatment group receiving the optimal observed dose achieved complete wound closure at 12 weeks compared with 46% in the fibrin control group,” commented Bert Slade, MD, FAAAAI, Chief Medical Officer at Healthpoint Biotherapeutics. “These findings underscore the importance of product

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design and cell delivery method to achieving wound closure, while also suggesting that, statistically, the odds of healing are 2.75 times greater for the cell-treated subjects compared to those receiving the fibrin matrix alone.”

The study was a randomized, double blind, dose-finding study involving subjects 18 years of age and older with venous leg ulcers of at least 6 weeks, but not more than 24 months duration. The ulcers must have been between 2 cm<sup>2</sup> and 12 cm<sup>2</sup> in area at presentation. A total of 228 subjects were enrolled across 35 investigational centers in the United States and randomized into one of four active treatment groups (N=46, 43, 44, 45) or control plus standard care (N=50). There were no statistically significant differences in baseline subject or wound characteristics.

“We are extremely pleased to have achieved this key development milestone for our novel biologic therapy and lead pipeline candidate,” said Travis E. Baugh, President and Chief Operating Officer of Healthpoint Biotherapeutics. “We look forward to meeting with the FDA to discuss our findings and agree upon the next steps in the regulatory pathway.”

Robert Kirsner, MD, PhD, will present the topline results of the study on August 4, 2011, from 1:30-2:00 pm, during the opening day of the inaugural meeting of the American College of Wound Healing and Tissue Repair held at The University of Illinois at Chicago. Dr. Kirsner served as one of the lead investigators for the trial, and is a tenured Professor and Vice Chairman in the Department of Dermatology and Cutaneous Surgery at the University of Miami Miller School of Medicine.

### **About Venous Leg Ulcers**

Venous leg ulcers are increasingly common and costly, and are often a cause of prolonged suffering for patients. These wounds can be characterized as difficult to heal and are typically caused by impaired microcirculation secondary to venous hypertension. Many venous ulcers fail to heal even after 3 months of standard treatment and develop into chronic, non-responsive wounds. Based on an estimated figure of 2.5 million venous leg ulcers in the United States alone and a study of actual direct treatment costs of \$9,685 per person, the annual cost of treating these wounds is likely in the many billions of dollars. Accordingly, the availability of innovative and effective treatment strategies for such high-risk wounds could provide tremendous benefits to both patients and society.

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### **About HP802-247**

HP802-247 is an investigational allogeneic living cell suspension that consists of two components that are sprayed sequentially on the wound bed at the time of treatment: a fibrinogen solution and a cell preparation containing a mixture of growth arrested, living, allogeneic epidermal keratinocytes and dermal fibroblasts.

Based on in vitro studies, HP802-247 is believed to release various growth and angiogenic factors into the micro-environment of the wound through administration of these living, metabolically active, but non-proliferating cells that are trapped on the wound surface in a thin fibrin matrix. The secreted growth and angiogenic factors are anticipated to stimulate the patient's own cells to heal the wound.

### **About Healthpoint Biotherapeutics**

Healthpoint Biotherapeutics is a biopharmaceutical company focused on the development and commercialization of novel, cost-effective solutions for dermal repair and regeneration. The company's research and development strategy is presently centered around next-generation cell-based therapies for the treatment of chronic wounds. Currently marketed products include Collagenase SANTYL<sup>®</sup> Ointment, OASIS<sup>®</sup> Wound Matrix, OASIS<sup>®</sup> Ultra Tri-Layer Matrix and REGRANEX<sup>®</sup> Gel. Healthpoint Biotherapeutics is also committed to advancing the care and treatment of wounds through support of industry leading continuing education from The Wound Institute<sup>®</sup>. To learn more about this comprehensive and award winning educational resource, please visit [TheWoundInstitute.com](http://TheWoundInstitute.com)<sup>®</sup>. Healthpoint Biotherapeutics is a DFB Pharmaceuticals, Inc., affiliate company, and is based in Fort Worth, Texas. For more information, visit the company website at [www.Healthpointbio.com](http://www.Healthpointbio.com).

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