



CoDa Therapeutics Achieves Positive Phase 2 Efficacy of NEXAGON[®] in Chronic Venous Leg Ulcers

69% Reduction in Venous Leg Ulcer Size in High-Dose Arm at 4 Weeks

31% of Wounds Completely Healed in High-Dose Arm at 4 Weeks

San Diego, California, May 25, 2010 – CoDa Therapeutics, Inc., a biopharmaceutical company focused on the development and commercialization of therapeutics for wound care and tissue repair, today announced positive results from its Phase 2 NOVEL Study of NEXAGON[®] in patients with chronic venous leg ulcers. NEXAGON[®] is a topically applied, novel therapeutic candidate, with the potential to revolutionize the wound healing treatment paradigm by leveraging a new mechanism and target involved in the healing process.

NEXAGON[®] achieved the endpoints of safety, reduction in wound size and complete healing after four weeks in the randomized, vehicle-controlled, double-blind, Phase 2 NOVEL study. Based on these compelling results, CoDa plans to initiate additional NEXAGON[®] studies and has scheduled a near-term end-of-Phase 2 meeting with the FDA to discuss potential registration studies to support marketing approval.

The three-arm trial randomized 98 patients at multiple sites to receive low or high dose NEXAGON[®] treatment or vehicle, in addition to compression bandaging (standard-of-care). After only three applications over a four-week treatment period, high-dose NEXAGON[®] demonstrated a 69% reduction in the size of venous leg ulcers. In addition, complete healing of 31% of wounds seen in the high-dose treatment arm was five times higher than complete healing in the vehicle arm. Importantly, no drug-related adverse events were observed in either of the low or high dose NEXAGON[®] arms, confirming favorable safety results from previous preclinical and Phase 1 clinical studies.

Dr. Thomas Serena, a NOVEL Study Investigator, and Founder and Medical Director of the Penn North Centers for Advanced Wound Care, said, “The data from CoDa’s Phase 2 NEXAGON[®] trial are very impressive therapeutically, especially considering the accelerated rate of complete wound healing and excellent safety profile after only four weeks of treatment. By targeting the inhibition of Connexin43, which may be a ‘master switch’ in wound healing, NEXAGON[®] is designed to improve both the rate and quality of tissue repair while managing inflammation. If patients can experience better and faster treatment outcomes, NEXAGON[®] has the potential to address significant treatment limitations and economic burdens imposed by chronic wounds on patients and insurers.”

In the U.S., venous leg ulcers account for the loss of 2 million working days and nearly \$3 billion in treatment costs each year. Duration of treatment may last over a year in certain cases, and frequently involves the use of significant healthcare resources, resulting in substantial costs for the U.S. healthcare system.

Dr. David Eisenbud, a vascular surgeon with expertise in wound evaluation and treatment, and former President of the American Academy of Wound Management, said, “The results from the Phase 2 NOVEL Study far exceed expected healing outcomes using today’s standard of care. As a physician focused on wound healing, my own venous ulcer patients would benefit tremendously from a treatment that closes their wounds by an average of nearly 70% in just four weeks. That is simply not achievable right now, and the NEXAGON[®] treatment results showing a 31% incidence of complete healing at four weeks are remarkable. The healing process tends to be much slower, and other chronic wound healing studies usually use a 12-16 week treatment period. Given the rapid and significant wound healing and safety results seen in the Phase 2 study, additional studies of NEXAGON[®] are highly warranted in patients with venous leg ulcers.”

In addition to Dr. Eisenbud, market research and interviews with practicing clinicians reveal that a product with the expected healing profile of NEXAGON[®] for chronic wounds would be seen as a major improvement over current standard of care treatments.



Bradford Duft, President and CEO of CoDa said, “After several years of intense work by a small and dedicated team, the results from this Phase 2 study represent an important milestone for CoDa. We are confident that the therapeutic potential of NEXAGON[®] will support our ongoing Series B financing and corporate partnering discussions. Chronic wounds represent one of the most significant unmet medical needs in the world today. The Phase 2 data support our conviction that CoDa’s Gap Junction Modulation technology is at the forefront of a potential paradigm shift in how we treat patients with venous leg ulcers and other chronic wounds. With our clinical development program mapped out, we are poised to contribute a major improvement in the quality and rate of wound healing for these patients as well as the U.S. healthcare system. We look forward to our upcoming end-of-Phase 2 meeting with the FDA, after which we will share the details of our future development plans.”

About the Phase 2 NOVEL Study

The NOVEL Study was a randomized, vehicle-controlled, double-blind Phase 2 clinical study to evaluate two doses of NEXAGON[®] in patients with venous leg ulcers. 98 patients (89 evaluable) were enrolled at sites in New Zealand and the United States, and randomized on a 1:1:1 basis to receive low or high dose NEXAGON[®] treatment or vehicle, in addition to compression bandaging (standard-of-care). Patients in all three treatment arms received three applications over a four-week treatment period. Study endpoints were reduction in wound size and complete healing after four weeks, as well as safety. Patients were evaluated at the end of treatment and are being followed for up to 12 weeks to further evaluate ulcer healing.

About Venous Leg Ulcers

For more than half a million patients in the U.S. suffering from venous leg ulcers each year, the wound healing process is often time-consuming and costly, and may gravely impact quality of life. Of all ulcer types, venous leg ulcers are the most common, resulting in the loss of 2 million working days and nearly \$3 billion in treatment costs per year in the US. The substantial costs associated with venous leg ulcers are related to the prevalence of the indication as well as the lengthy duration of treatment. The healing process for venous leg ulcers may take over a year in some cases and frequently requires significant healthcare resources during the healing process. Although venous leg ulcers place a significant burden on patients and the U.S. healthcare system, existing treatment options are unable to fully address this unmet need.

About CoDa Therapeutics Inc.

[CoDa Therapeutics](http://www.codatherapeutics.com) is a clinical stage biotechnology company focused on developing novel targeted therapies that address major unmet medical needs in inflammation, wound-healing and tissue repair. The company is pioneering a new field of science: gap junction modulation, using a new class of therapeutics that can modulate wound responses and reduce inflammation. CoDa has two open INDs and has completed one Phase 2 and two Phase 1 clinical trials in skin and eye, where NEXAGON[®] was shown to be safe and tolerable following administration to over 350 wounds on more than 125 subjects. CoDa’s technology, which can be conveniently applied topically, been shown to work across a wide variety of wound and inflammatory settings and conditions. CoDa presently has issued patents in the US, Europe and elsewhere, and pending applications in more than a dozen other patent families directed to methods and compositions for the treatment of acute wounds, chronic wounds, scarring, abnormal scarring, inflammation and pain, fibrosis, surgical adhesions, and orthopedic procedures, as well as combination therapies and improved medical devices. For further information, please visit www.codatherapeutics.com.

About NEXAGON[®]

The active ingredient in NEXAGON[®], which has been shown to work across a wide variety of tissues, is CODA001, a natural, unmodified antisense oligonucleotide that down-regulates the key gap junction protein connexin43 to dampen inflammatory responses and enhance healing. Data shows that for optimal healing connexin43 is normally dialed-down at the edges of acute wounds (i.e., wounds that will heal normally). Conversely, other data demonstrate that connexin43 is wrongly up-regulated at the edge of chronic wounds (i.e., wounds that are difficult to heal such as venous and diabetic ulcers). CoDa believes that one can better target available medical options and design more effective wound-healing alternatives by devising a therapeutic approach based on biological mechanisms naturally at work or conversely, at fault, in a given situation. The answer is thought to lie in connexin43, which can be seen as a “master switch” in wound healing that is temporarily turned “off” for superior healing of acute wounds, and when left “on” can lead to the unwanted inflammation and/or stalled healing characteristic of chronic wounds.



CoDa Therapeutics

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