

Generex Biotechnology Subsidiary Olaregen Therapeutix Inc. Plans Launch of FDA Cleared Excellagen® Wound Conforming Gel Matrix with Three Dosage Options

- Plans Commercial Launch of three dosing options for Excellagen in pre-filled syringes
- The 0.5 cc and 0.8 cc and 3.0 cc doses provide optimal wound coverage while reducing waste and costs
- 3 cc dose has utility in surgical applications for the treatment of larger wounds and surgical incisions
- In negotiations with major surgical wound care networks for treatment of diabetic foot ulcers, venous stasis ulcers, and difficult to heal wounds
- Nationally Renowned Wound Care Thought Leader, Dr. Peter A. Blume of Yale School of Medicine provides insight

MIRAMAR, FL, January 11, 2019 - Generex Biotechnology Corporation (OTCQB:GNBT) is pleased to announce that Olaregen Therapeutix Inc., a subsidiary of Generex Biotechnology will launch three doses of FDA 510K-Cleared, Excellagen, the company's wound conforming gel matrix that is designated as a Cellular & Tissue Based Product or CTP for wound healing. The 0.5 cc and a 0.8 cc syringes will be utilized to treat smaller wounds such as diabetic foot ulcers, venous stasis ulcers, and pressure ulcers, and in patients who have undergone MOHs surgery for removal of cancerous tissue. The 3cc syringe has been developed for larger wounds that are most frequently seen in emergency departments, operating rooms, and surgical suites. Excellagen has a designated reimbursement code in the Healthcare Common Procedure Coding System, with a unique Q Code designation 4149 referred to as a skin substitute.

The *Excellagen®* launch team is introducing the product in surgical centers, the Department of Defense and VA system, operating rooms, and wound care centers, as well as through podiatric practices. The company is currently in contract negotiations with major nation-wide surgical wound care centers for the use of Excellagen® for the treatment of a variety of wound types, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grfts, post-

Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. Additionally, NuGenerex Distribution Solutions, a wholly-owned subsidiary of Generex, will immediately launch Excellagen® through its MSO network of surgeons and podiatrists in five states.

“We’ve heard time and again about the issue of waste, or the need for multiple applications per a single procedure because the existing products don’t necessarily accommodate the size of the wound. This is not only time consuming for the doctor but is cost inefficient”, said Anthony J. Dolisi, Chief Executive Officer of Olaregen. “As part of our commitment to our customers, we listen carefully to their needs. After a thorough analysis of the market, and through discussions with physicians, we determined that Olaregen will launch Excellagen with multiple dosage options that offer clinical flexibility and cost savings with improved clinical outcomes.”

Dr. Peter Blume, D.P. M., F. A. C. F. A. S., Medical Director/HVC/Ambulatory Surgery, Yale New Haven Health Systems, Assistant Clinical Professor Of Surgery Anesthesia and Cardiology, Yale School of Medicine provides his views on Excellagen®, ““The average wound size in the surgical setting can be variable and quite large depending on the amount of debridement of soft tissue and bone. Olaregen’s decision to manufacture a 0.5cc and a 0.8cc for smaller wounds such as DFU, VSU and Pressure ulcers and a 3cc syringe for the surgical setting will not only save doctors time but will be highly cost effective and reduce product waste. The company is collaborating with physicians and surgeons with respect to the needs of the wound care community and addressing the unmet needs.”

The wound care market is extensive, with an estimated 77 million surgical wounds in the U.S., a percentage of which Excellagen is cleared for use. The wound conforming gel is also indicated to treat Diabetic Foot Ulcers (1,260,000), Venous Stasis Ulcers (1,625,000), and MOHs surgery (850,000) among the 17 wound types Excellagen is cleared to treat. Further, a recent study published in *Value in Health* (Volume 21, September 2018, 27 – 32) found that total Medicare spending estimates for all wound types ranged from \$28.1 to \$96.8 billion, as nearly 15% of

Medicare beneficiaries or 8.2 million people had at least one type of wound or tissue infection. These figures do not reflect the incidence of burns, amputations, and traumatic wounds and lacerations all which Excellagen is cleared for use. With the aging population and the increase in the incidence of diabetes, these numbers are expected to grow significantly in the future.

Anthony J. Dolisi, Chief Executive Officer provided his view of the market, “We have created a wound care expert salesforce to help guide physicians on the optimal Excellegen dose for a given wound type. As an example, in the surgical setting, a 3cc pre-filled syringe of Excellagen will cost substantially less than our CTP competitors with demonstrated improvements in healing rates. Olaregen is aggressively pursuing a “Value Based Healthcare” strategy in line with the goals of the Centers for Medicare and Medicaid Services, which has announced that they will be assessing waste in the wound care system. Discarding unused wound care products is a tremendous cost in the wound care space, so our strategy of multiple dosing options puts Olaregen in a strong market position.”

About Generex Biotechnology Corp.

Generex Biotechnology is an integrated healthcare holding company with end-to-end solutions for patient centric care from rapid diagnosis through delivery of personalized therapies. Generex is building a new kind of healthcare company that extends beyond traditional models providing support to physicians in an MSO network, and ongoing relationships with patients to improve the patient experience and access to optimal care.

In addition to advancing a legacy portfolio of immune-oncology assets, medical devices, and diagnostics, the Company is focused on an acquisition strategy of strategic businesses that complement existing assets and provide immediate sources of revenue and working capital. Recent acquisitions include a management services organization, a network of pharmacies, clinical laboratory, and medical device companies with new and approved products.

Our newly formed, wholly-owned subsidiary, NuGenerex Distribution Solutions (NDS), integrates our MSO network with a pharmacy network, clinical diagnostic lab, durable medical equipment company (DME-IQ) and dedicated call center.

About Olaregen Therapeutics

Olaregen Therapeutix, Inc. is a regenerative medicine company focused on the development, manufacturing and commercialization of products that fill unmet needs in the current wound care market. The company aims to provide advanced healing solutions that substantially improve

medical outcomes while lowering the overall cost of care. Olaregen's first product introduction, *Excellagen* (flowable dermal matrix) is a topically applied product for dermal wounds and other indications. *Excellagen* is a FDA 510K cleared device for a broad array of dermal wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/ grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds, enabling Olaregen to market *Excellagen* in multiple vertical markets. Additionally, *Excellagen* can serve as an Enabling Delivery Platform for pluripotent stem cells, antimicrobial agents, small molecule drugs, DNA-Based Biologics, conditioned cell media and peptides. Olaregen's initial focus will be in advanced wound care including diabetic foot ulcers (DFU), venous leg ulcers and pressure ulcers. Future products focusing on innovative therapies in bone and joint regeneration comprise the current pipeline. The company's mission is to become a significant force in regenerative medicine and advance the science of healing.

About our Service-Disabled Veteran-Owned Small Business (SDVOSB)

This a Service-Disabled Veteran-Owned Small Business (SDVOSB) that specializes in the sale, marketing, and distribution of innovative medical products through a nationwide network of veteran owned distribution services.



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Generex Contact:

Generex Biotechnology Corporation
Joseph Moscato
646-599-6222

Todd Falls
800-391-6755 Extension 222

investor@generex.com

Olaregen Contact:

Anthony J. Dolisi, Chief Executive Officer
anthony.dolisi@olaregen.com