MIRAMAR, FL, Sept 17, 2019/PRNewswire/ Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) today announced that the NSABP Foundation, Inc. (NSABP) has enrolled the first patient in the study: A Phase II Clinical Trial of Pembrolizumab in Combination with the AE37 Peptide Vaccine in Patients with Metastatic Triple Negative Breast Cancer (NSABP FB-14). The trial, conducted in conjunction with research partners Merck and the NSABP Foundation, is designed to evaluate the safety and tolerability of AE37 given in combination with KEYTRUDA® (pembrolizumab) as well as the objective response rate.

Eric von Hofe, President of NuGenerex-ImmunoOncology commented, “This is an exciting milestone for NuGenerex Immuno-Oncology, as we have now revitalized our AE37 development program with a focus on combination therapy with checkpoint inhibitors, which are now becoming standard of care for a broad array of cancers. Combining our promising immunotherapeutic with Merck’s checkpoint inhibitor, KEYTRUDA for the treatment of triple negative breast cancer represents a novel treatment strategy for a cancer of high unmet need. Prior studies with each agent alone showed promising signs of efficacy. By combining the mechanisms of checkpoint inhibition by KEYTRUDA with the robust, long-lasting and tumor-specific T-cell activation by AE37, we hope to enhance the clinical effectiveness of the immunotherapy strategies.”

Jason Terrell, MD, Chief Scientific and Medical Officer of Generex Biotechnology commented, “The start of patient enrollment represents the culmination of a committed effort by the team at NuGenerex Immuno-Oncology (formerly Antigen Express) and our research partners at the NSABP Foundation and Merck. NuGenerex Immuno-Oncology has been a pioneer on the forefront of immunotherapy for over a decade with our li-Key platform that ensures CD4 T-cell activation against any tumor antigen to which the li-Key is attached. The li-Key platform holds great promise, and we plan to initiate additional trials using the combination of checkpoint inhibitors with AE37 immune system activation in the field of personalized immuno-oncology to help patients in need of treatment options.”
Cautionary Note Regarding Forward-Looking Statements

This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

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 Therapeutix
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. Generex 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. Generex'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.

About Pantheon Medical
Pantheon Medical is a manufacturer of a physician friendly, “all-in-one”, integrated kit that includes plates, screws, and tools required for orthopedic surgeons and podiatrists conducting foot and ankle surgeries. Generex is developing and submitting several new product lines to the FDA which will include cannulated surgical screws, plates, and implants.
About MediSource Partners
MediSource Partners is a 10-year-old private company, currently contracted with over 25 vendors (including Pantheon Medical) for nationwide distribution of implants and devices for spine, hips, knees, foot, ankle, hand, and wrist surgeries. Additional product lines include biologics (blood, bone, tissue, stem cells), durable medical equipment, and soft goods. Generex also supplies kits to process bone marrow aspirates and platelet rich plasma biologics at the time of surgery.

Cautionary Note Regarding Forward-Looking Statements

This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

Generex Contact:

Generex Biotechnology Corporation

Joseph Moscato
646-599-6222

Todd Falls
1-800-391-6755 Extension 222
investor@generex.com