Generex Biotechnology Completes Acquisition of Regentys Corporation

- Announces closing of 51% acquisition of regenerative medicine company Regentys™
- Regentys Extracellular Matrix Hydrogel for the Treatment of Ulcerative Colitis and Other Inflammatory Bowel Diseases

MIRAMAR, FL, January 7, 2019/PRNewswire/ -- Generex Biotechnology Corporation (OTCQB:GNBT) is pleased to announce that the company has completed the acquisition of 51% of Regentys™ Corporation, a regenerative medicine company focused on developing novel treatments for patients with gastrointestinal (GI) disorders. The terms of the deal include the previously reported upfront payment of $400,000, plus $14.6 million to be paid according to a milestone-based schedule. Details of the transaction can be found in in the Generex 8K filing with the SEC.

The Regentys™ Extracellular Matrix Hydrogel (“ECMH”) is a first-in-class, non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis. ECMH is a proprietary, patented UC treatment that protects damaged tissue from waste flow and promotes tissue regeneration and healing rather than suppressing the immune system as other treatments currently do. The product has been developed with polymeric characteristics that transform ECMH from a liquid to gel form upon adherence to the mucosal lining of the diseased colon, providing a “Bio-Scaffold Bandage” to the affected area. The ECMH Bio-scaffold facilitates healing and functional repair of the colon lining, first by covering the ulcer to limit the inflammatory response, then by providing a framework to mobilize the body’s tissue repair mechanisms. Regentys has received guidance from FDA that the treatment can be approved through the FDA Office of Device Evaluation as a 510K de novo application, and the company will initiate the clinical studies necessary to obtain that approval by Q4 2019.

Ulcerative Colitis (“UC”), a disease that affects approximately 750,000 patients in the United States and 1.9 million patients worldwide, is a chronic, inflammatory disease that causes sores or ulcers in the lining of the large intestine (the colon). There are currently four biologics approved by FDA, including the top-selling antibody medicines Humira (adalimumab), Simponi (golimumab), Remicade (infliximab) and Entyvio (vedolizumab), all of which target the pro-inflammatory protein, TNF-α (Tumor Necrosis Factor Alpha). Even with the introduction of expensive biologics, more than half of all patients with ulcerative colitis [UC] do not achieve long-term remission. Many, because of disease progression, require colectomy surgery. Future indications for the company’s product platform include Crohn’s Disease, an inflammatory bowel disease, as well as rectal mucositis, a condition arising from cancer radiation treatments, conditions that affect millions of patients.
Joe Moscato, CEO of Generex commented on the acquisition, “The completion of this Regentys acquisition demonstrates our commitment to build a world-class regenerative medicine business by acquiring great companies with cutting-edge, patented technologies and exceptional management teams. Our direct investment in the clinical development of Regentys ECMH will provide long-term value to Generex investors as we achieve milestones on the path to commercialization in the billion dollar markets for ulcerative colitis and other inflammatory bowel diseases.”

Rick Bulman, CEO of Regentys™ continued, “Our partnership with Generex provides Regentys with a number of advantages, and we are happy to join the NuGenerex family of subsidiary companies. The merger agreement offers not only the financing to advance our clinical development efforts, but the Generex corporate philosophy also promotes continuity by supporting our scientific, medical, and leadership team with resources, relationships and industry knowledge that will accelerate the commercial introduction of Regentys ECMH.”

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.

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.

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