

Generex Biotechnology Expands Medical Device & Wound Care Portfolio with Acquisition of Regentys Corporation

Acquisition of Clinical Stage Developer of A Novel Hydrogel for the Treatment of Ulcerative Colitis and Other Inflammatory Bowel Diseases

MIRAMAR, FL, November 29, 2018/PRNewswire/ -- Generex Biotechnology Corporation (OTCMKTS:GNBT) is pleased to announce that the company has signed a Binding Letter of Intent to acquire 51% of Regentys Corporation, a regenerative medicine company focused on developing treatments for patients with gastrointestinal (GI) disorders. The company's first product, Regentys Extra-Cellular Matrix Hydrogel, is a first-in-class, non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis. 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. Generex made an initial payment of \$400,000 on November 28, 2018 to secure the agreement and the company is in the process of completing the legal documents with a plan to close the transaction in the coming weeks.

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 the disease, also require colectomy surgery. Future indications for the drug include inflammatory bowel disorder and irritable bowel syndrome, conditions that affect millions of patients.

The Regentys™ Extracellular Matrix Hydrogel ("RECMH") 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 RECMH 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 endogenous (the body's own) stem cells.

Jason Terrell, MD, Chief Medical and Scientific Officer of Generex stated, “The acquisition of Regentys and their patented Extracellular Matrix Hydrogel technology for tissue regeneration provides Generex with a high-value clinical stage asset. With the FDA guidance to a 510K *de novo* application for the treatment of Ulcerative Colitis, together with data from an extensive pre-clinical program, we have a clear regulatory path to approval. The RECMH product is well positioned as first line therapy for UC. The clinical trial process is rapidly advancing, and we will keep our investors apprised of results as they become available.”

Joe Moscato, CEO of Generex commented on the acquisition, “Our acquisition of and investment in Regentys will provide Generex with significant upside potential. We have worked closely with CEO Rick Bulman and his team to define the clinical and commercialization strategy, and we look forward to executing on our plan.”

Rick Bulman, CEO of Regentys continued, “Generex provides our company with an exceptional opportunity for the continued development of a remarkable clinical asset that has the potential to improve patient outcomes, reduce medical costs and better the quality of life of many UC patients. The Regentys family is very excited to collaborate with Joe and his team as they help transform the landscape of health care.”

About Generex Biotechnology

Generex is a strategic, diversified healthcare holdings company with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development. The Company’s direct-to-patient services support its strategy of all-inclusive access to doctors, diagnostics, therapeutics, and additional health-related services to greatly improve the patient experience in receiving care. On the provider side, Generex’s management services remove administrative burdens in multiple provider settings, including private practice and hospital, allowing doctors to devote more time to patient care. Revenue from the Company’s subsidiaries will support clinical advancement of its wholly owned therapeutic products with a focus in immunotherapeutics based on stimulating critical members of the immune response, known as T helper cells, and its proprietary buccal administration of insulin.

About Regentys

REGENTYS™ is a development stage, regenerative medicine company focused on developing treatments for patients with gastrointestinal (GI) disorders.

Our first product, ExtraCellular Matrix Hydrogel (ECMH), is a first-in-class, non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis.

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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