Generex Biotechnology Subsidiary Regentys Corporation Receives Approval of Japanese Patent for Extracellular Matrix Hydrogel (Regentys ECMH™)

MIRAMAR, FL, February 19, 2019 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) is pleased to announce that the company's subsidiary Regentys Corporation, a clinical stage regenerative medicine company focused on the treatment of inflammatory bowel diseases such as Ulcerative Colitis ("UC") and Crohn's Disease, was granted a Notice of Allowance for its patent application entitled "*Method And Composition For Treating Inflammatory Bowel Disease Without Colectomy*" in Japan:

- Method and Composition for Treating Inflammatory Bowel Disease (IBD) Without Colectomy
- Patented ECMH™ is a first-in-class non-pharmacological and non-surgical hydrogel therapy for Ulcerative Colitis (UC) and IBD

Ulcerative colitis is a chronic disease of the large intestine, where the lining of the colon becomes swollen and irritated, and sores appear, causing urgency, cramps, diarrhea, abdominal pain, and bleeding, resulting in loss of appetite and weight loss, fatigue and susceptibility to other diseases and a diminished quality of life.

An estimated 2 million people in Europe and 1 million in the United States are affected by UC, with an additional 220,000 patients afflicted in Japan. Studies indicate the prevalence of this disease has grown globally in the past 10 years, more particularly throughout Asia. Immunological in nature, UC is thought to be facilitated by a variety of hereditary, genetic and environmental factors and is increasingly being diagnosed in more urbanized areas.

Regentys' core technology platform, ECMH™, is a first-in-class non-pharmacological and non-surgical hydrogel therapy that functions as a "liquid bio-bandage" for the treatment of UC and other digestive diseases. The company's product uses a novel extracellular matrix enema solution that coats the digestive tract and gels at body temperature creating a therapeutic barrier to protect damaged tissue while facilitating reconstructive tissue remodeling as the body undertakes its natural healing processes.

Unlike 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) that attempt to suppress the immune system to control this disease, ECMH™ facilitates healing - not simply the management of disease symptoms.

The company previously received patent approval in the European Union for the company's ECMH technology, and patents are pending in the United States, elsewhere in Asia including China, Hong Kong, India and Korea, as well as other major industrialized nations throughout the world. Regentys expects to develop ECMH™ as a therapy to treat other inflammatory bowel diseases, including Crohn's Disease, which affects an estimated 1.1 million patients in the EU and U.S.

Regentys is currently undertaking activities to initiate its first-in-human trials in Australia expected in the fourth quarter of 2019. "We believe there is a strong global need for our core technology. Patent approval in Japan enables the company to address the growing Asian market for therapies to treat mild to moderate UC and Crohn's and other inflammatory bowel diseases ("IBD") said Rick Bulman, Chief Executive Officer of Regentys Corporation.

Richard Purcell, Executive Vice President of Research and Drug Development for Generex stated, "We are extremely pleased to have Regentys as part of the NuGenerex family of companies. As directed by FDA, the ECMH™ regenerative medicine technology is being advanced through the clinic under the 510K *De Novo* classification option, which provides an alternate pathway to classify novel devices of low to moderate risk. Just last December, FDA Commissioner Dr. Scott Gottlieb, issued a statement that FDA is providing a regulatory framework that sets clear standards, expectations and processes for *De Novo* classification as a way to continue to modernize the 510(k) process, thereby providing regulatory clarity for the clearance of ECMH™ based on our planned clinical program. We look forward to working with our partners on this exciting advance in the treatment of ulcerative colitis and inflammatory bowel diseases."

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 immuno-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 Regentys Corporation

Regentys Corporation (formerly Asana Medical, Inc.) is a regenerative medicine company developing a tissue engineered therapy for the treatment of Ulcerative Colitis (UC). The Company's product ECMH™, a novel application of a proven technology, will be a first-in-class therapy for patients suffering from Ulcerative Colitis. This therapy will offer a distinct departure from the current methods of treating UC patients in a multi-billion-dollar market dominated by immunosuppressive biologics and drug therapies that can have significant side effects. Additionally, 20-30% of patients do not benefit from these therapies and have no alternative except colon removal surgery. Regentys has an experienced management team, strong patent portfolio, world-class scientific and medical partners, and compelling preclinical proof-of-concept data. For more information, visit www.regentys.com.

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