

Generex Biotechnology Partner Regentys Corporation Receives European Patent Approval for ECMH™ for Treatment of Ulcerative Colitis -

- **Regentys Extracellular Matrix Hydrogel (ECMH™) Advances
Regenerative Medicine Approach for Inflammatory Bowel Diseases**

MIRAMAR, FL, December 14, 2018/PRNewswire/ -- Generex Biotechnology Corporation (OTCQB:GNBT) announced today that Regentys Corporation (formerly Asana Medical, Inc.), a clinical stage regenerative medicine company contracted to become a subsidiary of Generex, was granted European Patent No. 2983616 entitled "Method And Composition For Treating Inflammatory Bowel Disease Without Colectomy."

The Company's patent secures market exclusivity for its key product, Regentys ECMH™ is a novel application of extracellular matrix technology using a hydrogel bio-scaffold to enable the body to protect damaged tissue as it undertakes its natural healing process. Regentys ECMH™ is a first-in-class therapy for patients suffering from Ulcerative Colitis (UC), an inflammatory bowel disease that affects an estimated 2 million people in Europe and 1 million in the United States. This specific patent provides exclusive market protection in the European Union for the company's ECMH™ technology that is being developed for global markets; patents are pending in the United States and China. In addition to the UC treatment indication, Regentys is developing ECMH™ to treat other inflammatory bowel diseases, including Crohn's Disease, which affects an additional 2 million people in the EU and U.S.

"As we advance our platform approach for the treatment of ulcerative colitis, and other inflammatory bowel diseases ("IBD"), we are mindful of the value of building an intellectual property portfolio that supports our proprietary formulations, applications and therapies," said Rick Bulman, Chief Executive Officer of Regentys Corporation. "We are pleased to have been granted the '616 patent as a recognition of our efforts. UC really impacts the quality of life of patients and we look forward to advancing our translational research program into the clinic, where we expect to initiate first-in-human studies of Regentys ECMH™ in Q3 2019."

In late November 2018, Generex Corporation entered into a binding letter of intent to purchase 51% of Regentys. As a consequence, Regentys received a \$400,000 upfront payment on the \$15,000,000 purchase price, the bulk of which will support the clinical trials required by regulatory authorities for the commercialization of ECMH™. Mr. Bulman commented, "Upon closing the pending deal with Generex, which is almost complete, we look forward to operating as a subsidiary of NuGenerex Therapeutics (a wholly-owned subsidiary of Generex), and advancing ECMH™ through the clinical and regulatory process. We look forward to positive clinical results and believe our collaboration with the Generex team will help us realize substantial benefits through a more efficient regulatory approach and reduced time to approval and market commercialization in the EU and US. The closing documents are in final stages and we expect corporate approvals in the coming weeks."

Joseph Moscato, CEO of Generex stated, “We view the opportunity to help Regentys commercialize its technology as a unique opportunity to address an unmet need in a \$6 billion global market for inflammatory bowel diseases. Their novel approach to the treatment of ulcerative colitis provides UC patients with a targeted non-surgical solution to help the body heal rather than using immunosuppressant therapies, expensive antibody therapies, or surgically removing diseased sections of the patient’s colon. With 20-30% of UC patients requiring surgery to help combat this disease, any relief the Regentys ECMH™ hydrogel can provide to minimize the effects of UC or disrupt the progression of the disease would be extremely beneficial to the millions that now suffer from this debilitating disease who can’t get true relief. We welcome Regentys to the family of NuGenerex Therapeutics companies.”

About Generex Biotechnology Corp.

Generex Biotechnology Corp. ([GNBT](#)) is a biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines. Our company creates value for stockholders by providing a diversified portfolio of biotech and pharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure.

The company goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable, diversified and lower-risk business than a typical biotech company. Our business model is based on doing what we do best: drug discovery, early-stage drug development, product reformulation and partnering. We partner with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) to ultimately generate our revenue.

About Ulcerative Colitis

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

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. 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 biologic- 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 protection, world-class scientific and medical partners, and compelling preclinical proof-of-concept data. For more information, visit www.regentys.com.

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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