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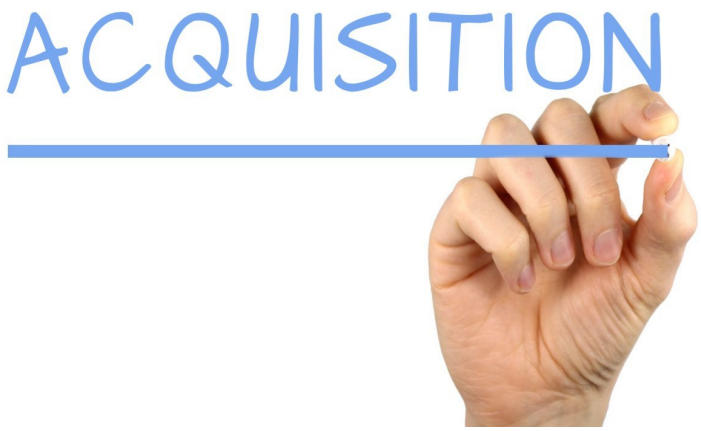
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Generex Biotechnology acquires Regentys Corporation

08 January 2019 | News

The Regentys Extracellular Matrix Hydrogel is a first-in-class, non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis.



Generex Biotechnology Corporation has announced 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 the Generex 8K filing with the SEC.

The Regentys Extracellular Matrix Hydrogel 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, 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? (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 (Research and consulting firm GlobalData reports the global ulcerative colitis surgery space is set to rise from $5.64 billion in 2015 to over $6.58 billion by 2025).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.”