FCX-013

FCX-013 is an autologous fibroblast

FCX-013 genetically-modified using lentivirus and encoded for matrix metalloproteinase 1 (MMP-1), a protein responsible for breaking down collagen. FCX-013 incorporates Precigen's proprietary RheoSwitch Therapeutic System® (RTS®), a biologic switch activated by an orally administered compound (Veledimex) to control protein expression at the site of the localized scleroderma lesions.

FCX-013 is designed to be injected under the skin at the location of the fibrotic lesions where the genetically-modified fibroblast cells will produce MMP-1 to break down excess collagen accumulation. With the FCX-013 therapy, the patient will take an oral compound (Veledimex) to facilitate protein expression. Once the fibrosis is resolved, the patient will stop taking the oral compound which will control further MMP-1 production.

The U. S. Food and Drug Administration (FDA) has granted allowance of Fibrocell's Investigational New Drug Application for FCX-013 to begin clinical trials for the treatment of moderate to severe localized scleroderma.

The FDA has granted Orphan Drug Designation to FCX-013 for the treatment of localized scleroderma. In addition, FCX-013 has been granted Rare Pediatric Disease Designation and Fast Track Designation for the treatment of moderate to severe localized scleroderma.