Hydrogel Implant Demonstrates Impressive Recovery Rates for Patients with Knee Cartilage Damage

Regentis Biomaterials

Treatment shows potential as a safe and highly effective for articular cartilage injuries

Regentis Biomaterials announced today new clinical data demonstrating the efficacy and safety of its GelrinC implant for treating articular cartilage in injured knees. As presented at the International Cartilage Repair Society World Congress in Izmir, Turkey, the clinical results demonstrated sustained knee function improvement over 24 months after implantation and significant pain reduction. In addition, the clinical safety data showed that adverse effects were limited and comparable to those reported in similar studies with no serious adverse events related to the implant.

“These results show that GelrinC is safe and that the treatment effectively regenerates high quality cartilage,” said Regentis Biomaterials president and CEO Alastair Clemow. “While recovery rates for knees treated with standard procedures plateau and even decrease over time, GelrinC patients showed constant improvement over the course of the study.”

Articular cartilage is the smooth, white tissue covering the ends of bones where they come together to form joints. In the knee, this cartilage can be damaged by a traumatic sports accident or a bad fall. A painful injury for patients, repairing articular cartilage is a challenge for doctors to treat since the tissue has no capacity to heal itself.

GelrinC is a biodegradable hydrogel implant designed to treat cartilage defects in the knee. It is administered as a liquid to fill any shape of cartilage defect and it is then converted into a solid after 90 seconds of exposure to ultra-violet light. The GelrinC implant naturally degrades within 6-12 months and is replaced with functional and durable cartilage.

After two years of study, patients had a substantial improvement of the Knee injury and Osteoarthritis Outcome Score (KOOS), excluding the sports subscale, of 23.6 points at 18 months, representing a 43% improvement, and 32.9 points at 24 months, representing a 60% improvement (52.6 vs. 84.1). KOOS is a patient-reported outcome measurement instrument developed to assess a patient’s opinion about their knee and associated problems. Scores from the international knee documentation committee (IKDC), another measure of patient progress, were even more impressive. The subjective questionnaire showed an improvement of 86% at 18 months and 94% at 24 months (40.4 vs. 78.4).

“These results are particularly strong when you compare them against those achieved through standard procedures, such as microfracture, which increase the flow of blood and bone marrow stem cells to the damaged area,” said Dr. Ron Arbel who will present the study’s outcome at ICRS 2013 and is a study investigator. “GelrinC works in combination with the microfracture procedure to greatly enhance the body’s ability to regenerate new cartilage so that patients can return to an active lifestyle.”

Radiological evaluation by MRI scans demonstrated that newly developed cartilage structure was similar in its quality to native cartilage. These measurements were obtained by using traditional techniques and quantitative T2 mapping which evaluate changes in the quality of the regenerated cartilage.

“MRI evaluations with combined morphologic and biochemical assessment allowed us to monitor patient progress made with GelrinC,” said University of Vienna medical professor Dr. Siegfried Trattnig who will present the radiological outcome of the patients at ICRS 2013. “We were able to understand using noninvasive magnetic resonance techniques how new tissue integrated with the host tissue, as well as the biochemistry behind the repair tissue.”

The clinical results came from a single-arm, multi-center study that involved 23 patients in Europe and Israel. An additional 30 patients are currently enrolled at 12 new sites in Germany, Belgium, Poland, the Netherlands and Israel.

CE mark-approved, GelrinC is an investigational device and is not available for sale in the U.S. and Israel.